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IN THE

Supreme Court of the United States

OCTOBER TERM, 1975

No. 75-839

ROBERT P. WHALEN, as Commissioner of Health of the State of New York,

Appellant,

against

RICHARD ROE, an infant by ROBERT ROE, his parent; JOHN DOE, an infant by MARY DOE, his parent, JAMES MOE, an infant by MICHAEL MOE, his parent; JANE POE, MATTHEW T. BRODY, ISRAEL L. SCHMIERER AND EMPIRE STATE PHYSICIANS GUILD, INC.,

Appellees,

and

GEORGE PATIENT, MARTHA PATIENT, GERALD L. LUSTIG, and THE AMERICAN FEDERATION OF PHYSICIANS AND DENTISTS,

Intervenor-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

JURISDICTIONAL STATEMENT

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1975

No. 75

ROBERT P. WHALEN, as Commissioner of Health of the State of New York,

Appellant,

against

RICHARD ROE, an infant by ROBERT ROE, his parent; JOHN DOE, an infant by MARY DOE, his parent, JAMES MOE, an infant by MICHAEL MOE, his parent; JANE POE, MATTHEW T. BRODY, ISRAEL L. SCHMIERER AND EMPIRE STATE PHYSICIANS GUILD, INC.,

Appellees,

and

GEORGE PATIENT, MARTHA PATIENT, GERALD L. LUSTIG, and THE AMERICAN FEDERATION OF PHYSICIANS AND DENTISTS,

Intervenor-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

JURISDICTIONAL STATEMENT

Appellant appeals from a final judgment of the United States District Court for the Southern District of New York entered on October 9, 1975, which declared uncon-

stitutional New York Public Health Law §§ 3331(6), 3332 (2)(a), and 3333(4), insofar as they required the filing of official New York State prescriptions containing patient identity with the appellant and further enjoined the enforcement of the statutes. This statement is submitted pursuant to Rule 15 of the Rules of the Supreme Court of the United States.

Opinions Below

The opinion of the District Court originally denying the application to convene a three-judge court pursuant to 28 U.S.C. §§ 2281 and 2284 and dismissing the complaint is reported below at 357 F. Supp. 1217.

The opinion of the Court of Appeals for the Second Circuit reversing the order of the District Court and remanding for the convening of a three-judge court is reported below at 480 F. 2d 102.

The opinion and order of the three-judge court denying a preliminary injunction to plaintiffs and also denying a motion to dismiss to defendant is reported below at 364 F. Supp. 536.

The opinion of the three-judge court decalaring the statutes involved unconstitutional and granting to plaintiffs a final injunction is not yet reported. It is reproduced herein as Appendix "A" (1a).

Jurisdiction

These consolidated actions were brought pursuant to 28 U.S.C. § 1343(3) and 42 U.S.C. § 1983, to declare unconstitutional and enjoin the operation of New York's Public Health Law Art. 33 (§§ 3300 *et seq.*) as required the use of official New York State prescriptions for the prescribing and dispensing of Schedule II drugs; specifically §§ 3331

(6), 3332(2)(a) and 3333(4), as to patient identity. The final judgment of the District Court was entered October 9, 1975. The defendant filed his notice of appeal on October 20, 1975. Copies of the judgment and notice of appeal are reproduced herein as Appendices "B" (14a) and "C" (18a).

The jurisdiction of the Supreme Court to review the decision and judgment herein is conferred by 28 U.S.C. §§ 1253 and 2101(b).

Statute Involved

New York Public Health Law (P.H.L.) §§ 3331(6), 3332(2)(a), and 3333(4). These provisions require filing of the official prescriptions which by 3332(2)(a) contain a patient's name and address.

There are:

P.H.L. § 3331 (6):*

> "6. A practitioner dispensing a substance which may be prescribed only upon an official New York state prescription must at the time of such dispensing prepare an official New York state prescription in the manner set forth in subdivision two of section thirty-three hundred thirty-two of this article. The practitioner shall retain one copy for five years and shall file the original and one copy with the department by not later than the fifteenth day of the next month following the month in which the substance was delivered. This requirement shall not apply to the dispensing by a practitioner pursuant to section thirty-three hundred fifty-two of this article."

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* Actually only P.H.L. § 3332(2)(a) refers to the contents of the triplicate prescription, which is upheld but without patient identity on the filed copies.

P.H.L. § 3332 (2) (a):*

"2. Such prescription shall be prepared in triplicate, writen with ink, indelible pencil or, apart from the practitioner's signature, typewriter. The original and both copies must contain the following:

(a) the name, address and age of the ultimate user for whom the substance is intended, or, if the ultimate user is an animal, the species of such animal and the name and address of the owner or person in custody of such animal;"

P.H.L. § 3333 (4):*

"4. The endorsed original prescription shall be retained by the proprietor of the pharmacy for a period of five years. The endorsed copy of such prescription shall be filed with the department by not later than the fifteenth day of the next month following the month in which the substance was delivered."

Other portions of Article 33 of the New York Public Health Law are possibly involved and are set forth in appendix "D". (20a)

Questions Presented

1. Was the District Court correct in concluding that New York did not need patient identity on filed prescriptions to achieve a legitimate state purpose?

2. Did the filing requirement invade any constitutionally protected right of privacy of the plaintiffs?

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* Actually only P.H.L. § 3332(2)(a) refers to the contents of the triplicate prescription, which is upheld but without patient identity on the filed copies.

3. Did the plaintiffs have standing or present a real case in face of the strict confidentiality provisions in the law?

(a) Can unsubstantiated "fears" support an actual case or controversy?

4. Is it proper to test the constitutionality of the filing statute in question by a "compelling state interest" requirement?

Statement of the Case

There are two actions for declaratory and injunctive relief brought pursuant to the Civil Rights Law to invalidate a state statute, which requires that all prescriptions for Schedule II drugs, P.H.L. § 3306 (Schedule II) be prescribed and dispensed on official New York State prescriptions, with one copy thereof to be filed with the defendant and his Department of Health. The complaints sought to invalidate P.H.L. §§ 3331(6), 3332(2)(a), and 3333(4)*, as to any requirement that disclosed patient identity to the State.

Thus, plaintiffs Richard Roe (a fictitious name) *et al.* (hereinafter called "Roe") commenced the action in the United States District Court for the Southern District of New York against the defendant (appellant) for a judgment, as noted. The complaint centered on the use of official state prescription forms. The action was filed on March 29, 1973 via an order to show cause. Plaintiffs George Patient et al. (hereinafter called "Patient") commenced a similar action, attacking the same statute. That complaint was filed April 3, 1973.

Roe by order to show cause, signed March 29, 1973, moved for the convening of a three-judge court and for a

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* The Patient plaintiffs intervened; 357 F. Supp., at 1219, ftn. 5.

preliminary injunction. A temporary stay of administrative implementation of the law, in part, was granted. On the return date, April 6, 1973, Patient was allowed to intervene, but the complaint was dismissed as raising no substantial constitutional issue. (357 F. Supp. 1217). The stay of full implementation was dissolved.

Roe and Patient took an appeal to the Court of Appeals for the Second Circuit. The stay of implementation, in part, was reinstated pending appeal by the Circuit. The State could not process prescription forms received. The Court of Appeals reversed the dismissal of the complaint and remanded the action to the District Court for the convening of a three-judge court. The stay, or temporary restraining order, as modified, was continued pending the hearing before the District Court (480 F. 2d 102).

On remand, the statutory District Court denied both Roe and Patients' motions for a preliminary injunction and the state's motions to dismiss.* (364 F. Supp. 536).

The State filed an answer and extensive discovery thereinafter ensued. A trial was held on December 2, 1974 before the Court. Evidence was also received by way of (1) stipulated facts, (2) depositions taken on December 4 and 6, 1974 and (3) exhibits. The District Court filed its unanimous opinion on August 13, 1975 (App. A). The opinion held "that so much of the New York [Public] Health Law as requires reporting to state authorities in Albany the names and addresses of patients who receive Schedule II drugs as medication by duly licensed physicians is an unconstitutional interference with plaintiffs' rights of privacy guaranteed under the Fourteenth Amendment." (13a).

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* The filing statute did not go into full force and effect until the Court of Appeals vacated preliminary injunctions in two similar actions on September 11, 1973, *New York State Physicians Union* v. *Ingraham* (W.D.N.Y., Civil 1973-248, Civil 1973-281). We are aware of no further proceedings therein.

On October 9, 1975, the District Court signed an order which contained a stay suggested by the Roe attorneys. The order (1) declared unconstitutional Public Health Law (N.Y. §§ 3331[6], 3332[2][a] and 3333[4]) as they require disclosure of patient identity; (2) enjoined defendant from enforcing the above provisions and accepting such prescriptions or any other document disclosing patient identity for filing; and applied this to any other agency of the State (although appellant has no control over them and none were parties); (3) required defendant to destroy all records within 60 days; and (4) file an affidavit to that effect.

The District Court stayed (3) and (4) pending defendant filing an appeal. However, appellant had to place all computer tapes and forms in a sealed vault and he could no longer add names to or make any record from the tapes of patient names. As a consequence patient identity from prescriptions is no longer available to the state via the statute.

The appellant then applied to Mr. Justice Thurgood Marshall, Circuit Justice, for a stay of judgment. After hearing argument, Justice Marshall denied the stay in an opinion dated October 28, 1975 (Appendix "E" herein, 39a).

Facts of the Case

The plaintiffs-appellees in both actions are anonymous patients and named doctors and doctor's organizations. The suits were started on the eve of the effective date of Article 33 of the Public Health Law. The challenged portions of the statute required that on or after April 1, 1973, a practitioner (physicians and others) would have to use an official New York state prescription for prescribing Schedule II drugs, a limited list of narcotic and like substances. Pharmacists could only sell such drugs on the official prescriptions, with exception for emergencies (P.H.L. § 3334).

The official prescription is dispensed in triplicate and only on special order to practitioners. It is required to have certain specified information (P.H.L. § 3332) including patient's name, address and age (§ 3332[2][a]). After the drug is dispensed the pharmacist must file a copy with the Department of Health (3333[4]), or if the practitioner self-dispenses, he must file a copy in similar manner (3331 [6]).

The purpose of the filing requirement is found in the legislative history. As stated in the Interim Report of the Temporary State Commission to Evaluate the Drug Laws (N.Y.S. Legislative Documents [T.S.C] [1972] No. 10) at p. 21:

> "Once the department has received the copies, it will be able to compile data which will uncover irregularities such as forgeries, fraudulent obtaining of schedule II substances, and thefts of prescription blanks and their misuse by unauthorized persons. The information received by the department will show if a patient has obtained prescriptions by going from doctor to doctor, or if stolen prescriptions are being used. This procedure will also indicate where there has been an over-prescribing or over-dispensing of schedule II drugs. There is a 30-day maximum on the amount of any controlled substances which may be dispensed. Prescriptions for schedule II substances may not be refilled (§ 3339)."

There was no pretense or expectation that multiple prescription and monitoring would solve all problems of drug abuse. Thus at p. 22 of the Interim Report:

> "The Commission has no illusion that the multiple prescription requirement and monitoring of the prescriptions by the departemnt will affect the far more significant problem of street abuse, particularly of the contraband drugs. We do believe, however, that it will be a significant step in reversing the growing trend of diversion and of 'legitimate' abuse of dangerous drugs."

The expectation was that upon filing the data (including patient identity) from the prescription it would be encoded. This via modern data processing techniques (computers). See Second Interim Report of the T.S.C. April 5, 1971, which reviewed the possible uses of triplicate prescriptions. Also cited were the operation of similar systems for varying periods in California, Idaho and Illinois.* Noted was their experience and the conviction that "such a program in New York will result in a marked decrease in the abuse of legitimately prescribed drugs" (p. 21). In other words, triplicate prescriptions and filing can have a prophylactic affect in this area.

As noted in the opinion of the Court, the Schedule II drugs, while of some accepted or restricted medical use, also have a high potential for abuse. The monitoring of these drugs by the use of triplicate prescriptions seeks to prevent these drugs from being diverted to illegal uses.

The plaintiffs patients objecting to the filing of their names on the filed prescriptions, contended the statute was an invasion of their constitutional right of privacy. The doctors contended that the filing interfered with their constitutional right to practice their profession and prescribe medication or drugs as they saw fit. As such, it was claimed the law infringed on the confidentiality of the doctor-patient relationship.

Basically the plaintiff envisioned that the data collected would be misused, *i.e.*, that they would be labelled "drug addicts", the data would not remain confidential, and the

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* California Health & Safety Code §§ 11158, 11160, 11167; Idaho Code, §§ 37-2722, 37-2730, Ill. S.H. Ann., Ch. 56½, §§ 1308, 1311, 1312(a).

like. The actions were begun on or before the complete effective date of the filing requirement, as complete filing and computerization of the prescriptions was delayed until September, 1973 due to various court orders. Thus the above proposition was a complete supposition.

There was a trial and the testimony of the plaintiffs' witnesses is summarized (5-6a) the actual operation of the triplicate was only described by the opinion (11a) to include the use of patient identity, in printing out lists of patients obtaining more than a 30-day supply of Schedule II drugs or going from doctor to doctor to obtain Schedule II drugs.* Actually other uses were testified to (specific inquiries from the field). Even in the specific area, the cited single instance (11a) has been joined in the months following trial by dozens of suspect situations revealed by increased scrutiny of printouts. Obviously this could not be reflected in the record. Of course if filing totally met the Legislature's hopes, no one would violate the law and no suspect situation would exist.

Based on this supposed lack of *results,* the Court below concluded that the State did not *need* patient identity on the filed prescriptions and enjoined the filing or processing of prescription forms containing patient identity.** The order signed prevented permanently any use of patient identity to better enforce Article 33 of the P.H.L. A limited stay allowed the defendant to keep previously processed prescriptions but not make any use of them.

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* No plaintiff patient testified he would be on the print-out, nor did any doctor testify he would be on the print-out.

** The opinion held it was "unnecessary" to evaluate confidentiality requirements (13a).

The Questions Presented on This Appeal Are Substantial

1. There is serious doubt whether the plaintiffs had standing to sue or presented a real case or controversy

In the opinion of the District Court it was necessary to assume that a undifferentiated "fear" of computerization gave standing to the plaintiff patients to challenge not just computerization but the filing of the triplicate prescriptions themselves. Thus it was stated (10a):

> "When these physical illnesses and disabilities require as here treatment by drugs which, in light of the current epidemic of drug abuse in the society, are under governmental control and regulation, there is legitimate concern that information that one, one's children or an intimate is under treatment with such drugs not be broadcast to unauthorized sources. There is fear that the adults or children will be stigmatized if their use of the drug becomes known. There is no question but that the statutory requirement challenged here intrudes upon and interferes with the doctor-patient relationship."

Yet there was absolutely no testimony at trial that the information would or could be "broadcast to unauthorized sources" (§ 3371 prohibits unauthorized disclosure). The opinion could only state the "fear" of stigmatization. On the other hand the state effort to control drug abuse and prevent illicit trafficking in dangerous drugs was and is a legitimate state purpose. Despite this the Court concluded that the statute intruded on the doctor-patient relationship and had a needlessly broad sweep. In this regard it had to use the "compelling state interest" test, and expanded it beyond the decisions of this Court. Courts are not to apply the fundamental-interest analysis lightly. *San*

Antonio Ind. School District v. *Rodriguez,* 411 U.S. 1, 18, 44 (1973).

Ignored in the opinion is the fact that the law protects confidentiality by limiting strictly the information, as well as the possble uses of that information; P.H.L. § 3371. This negates any invasion of privacy. The decision also ignored the plain legal facts of the original decision. To quote, 357 F. Supp. 1217, at 1221:

> "First, this is not a case where the state has launched a broad scale invasion into the doctor-patient relationship requiring the publication of the entire medical history and treatment record. Indeed, contrary to plaintiffs' suggestion, even the illness for which the Schedule II drug is prescribed need not be revealed.
>
> "Second, the statute *on its face* does not permit unrestricted divulgence of even the limited information collected. In fact § 3371 confines disclosure to the extent consistent with the purposes of the Act. I have also been presented with the memorandum of Assemblyman Hardt and the affidavit of Commissioner Whalen, both of whom appear to be taking all necessary steps to maintain the security of the computerized information.
>
> "Finally, this is not a case where the plaintiffs have been able to prove actual abuse of the reporting and computerizing process and consequently to argue facial unconstitutionality based upon pragmatic or historical evidence; that is that such process necessarily and inevitably results in abuse." (emph. suppl.)

Plaintiffs' testimony at trial clearly showed they simply were ignorant of the law's confidentiality provisions (P.H.L. § 3371); and of the five year limitation on records; or the State had ever "broadcast" their records, in any

manner. There can be no doubt that the plaintiffs were not failing to receive medication due to the statute or any of defendant's action. Clearly the statute infringed no "fundamental interest" of plaintiffs.

The plaintiffs were ignorant of the fact that defendant always had access to their prescriptions, even before the passage of the statute involved. Once again the Court ignored this obvious point which negates any impermissible invasion of a constitutionality-protected right by reason of this statute. The failure to advert to this is anomalous in view of its recognition in the earlier opinion in this case in which the single district judge said in dismissing the complaint (357 F. Supp. 1217, at 1221-1222):

> "In order to further appreciate the essence of plaintiffs' privacy argument, it is necessary to consider the status of the law prior to April 1, 1973. Insofar as the issues involved in this lawsuit are concerned, the only effective distinction is that the new statute requires sending a copy of each prescription for Schedule II drugs to Albany to be computerized. Previously prescriptions required the name of the patient, N.Y. Public Health Law § 3301(32) (McKinney 1971) (repealed 1973), the pharmacist was required to keep a copy of the prescription, *Id.* at § 3322, and law enforcement officials had complete access to the druggists prescription files, *Id.* at §§ 3322(1) (c), 3334. In short, the state had the power to learn all that it may now require to be revealed. The only difference is that now the state has developed the means to *make effective use* of that basic power which remains unchallenged." (Emphasis supplied)

It was only by ignoring these obvious points that the three-judge court could conclude the plaintiffs had a real case. It even had to ignore its own prior decision, 364 F. Supp. 536, finding "no evidence of any immediate in-

jury", id. at 546, see also 545. The plain fact was that after some 15 months of computerization, at time of trial (Deecmber, 1974),* no plaintiff or anyone else, could show any injury from filing or computerization.

On the other hand, this appeal raises a serious issue as to the control of drug abuse, a fact of life to thousands of people, many of them the recipients of Schedule II drugs, obstensibly for medical purposes. This was a strong factor in the three-judge court originally allowing computerization to go forward. 364 F. Supp. at 546:

> "It should be noted, however, that the state's efforts are directed against a very real and pressing emergency requiring immediate and effective response."

The decision however ignored this emergency and plaintiffs' baseless fears were given the force of law. To condemn computerization because of its efficiency strikes at many vital governmental functions.

It has been held that such "fear", does not support a case of action. *Laird* v. *Tatum,* 408 U.S. 1, 13-14 (1972). What makes this an even stronger case than *Laird,* is the fact the filing and computerization herein is authorized and controlled by a specific statute, directed to a specific and real problem. This is not a case of bureaucrats administratively setting up a computer data-bank. Rather the Legislature saw the need for this compilation and passed specific legislation after much study. (See Interm Reports of Temporary State Commission to Evaluate the Drugs Laws).

The "danger" to plaintiffs was and is hypothetical, based on unsupported assertions that the clear provisions

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* This, contrary to the decision (11a) statement of a 20 month life. Earlier stays delayed computerization. Further the computer was not fully operational for many months, since testing was necessary.

of the very law they are challenging would not be observed —as to confidentiality and length of record keeping.

The decision ignored the testimony that other public officials such as school nurses had records of children taking ritalin, a Schedule II drug. (This drug apparently reduces hyperkenesis, but also has serious side effects).

Remote claims of risk of disclosure do not support a cause of action. *California Bankers Ass'n* v. *Schultz,* 416 U.S. 21, 56-57 (1973). This case upheld a federal bank record-keeping and reporting statute against constitutional challenge.

While standing has been expanded by this Court, it is the law that pleadings (and proof) "must be something more than an ingenious academic exercise in the conceivable." *United States* v. *SCRAP,* 412 U.S. 669, 688 (1973).

> "A plaintiff must allege that he has been or will in fact be perceptibly harmed by the challenged agency action, not that he can *imagine* circumstances in which he could be affected by the agency's action. And it is equally clear that the allegations must be true and capable of proof at trial." (Emphasis supplied)

The "proof" in the instant case was that the plaintiffs "imagined" harm and took action on such "visions." Yet with one or two exceptions all received their medication, negating interference with medical practice. Any refusal to accept medication was based on a self-fulfilling prophecy that at some time in the future the data on prescriptions would be misused. Such absurd reasoning cannot support a case. Courts do not engage in vacuous speculation that public officials may not observe statutes or regulations as to confidentiality. *Sanders* v. *Wyman,* 464 F. 2d 488, 491, ftn. 3 (2d Cir. 1972), *cert. denied* 409 U.S. 1128. Even "fears" as to others do not give standing. *Moose Lodge No. 107* v. *Irvis,* 407 U.S. 163, 166 (1972).

Certainly *California Bankers Ass'n, supra,* at 68-69, gives no support to conjectural pleading and proof which is all the instant case contains.*

The District Court struck down an important part of a legitimate state statute on the basis that anonymous patients *might* be harmed by filing if the state did not observe the statute (P.H.L. § 3371) on confidentiality. Also ignored was the five year limitation on keeping of records. (P.H.L. § 3370[3]) which obviously showed no one was branded for life or a child, years later, could have his prescription records revealed.

The assumption of standing by the court below, 364 F. Supp. at 340, ftn. 6, is questionable. The claims herein were premature and still are. See *Association of American Physicians and Surgeons* v. *Weinberger,* 395 F. Supp. 125 (N.D. Ill. 1975), *aff. sub nom. Association of A.P. & S.* v. *Matthew,* —— U.S. —— 44 L.W. 3394 (Nov. 18, 1975). The above case clearly indicates that official review of a physician's practice does not interfere with any constitutional right to practice medicine or invade the privacy of patients. The statute involved protected confidentiality by coding, 42 U.S.C. § 1320, c-4(c). In similar manner P.H.L. § 3371 protects confidentiality of patient identity by limiting access. Yet while the three-judge court in the *Association* case pointed to the provision as negating any possible invasion of privacy, the court below ignored New York's provision.

2. The need for filing and patient identity was determined by the Legislature

The District Court simply assumed that the State could accomplish all the purposes of the triplicate prescription if patient identity was deleted from the filed prescriptions

* The Court below seemed to recognize, at one point, that plaintiffs' arguments were fallacious. *Roe* v. *Ingraham,* 364 F. Supp. at 545.

(11a). However this assumption ignores the purpose of the Legislature in enacting Article 33 and, in particular § 3332(2)(a), as to the contents of both the original and both copies of the prescription. The Legislature determined the need for patient identity, not the named defendant or his employees. Even if the computerization of patient names was necessary only in the area of patients obtaining more than a thirty day supply or going from doctor-to-doctor this problem was not beyond the power of the Legislature to address itself to. Furthermore, there was in the record proof that specific inquiries on users were being processed on a request basis.* And the decision ignored the use of filed prescriptions containing patient identity in checking on forgeries and raised prescripitions. Also contemplated by 3371(2) was use of the filed prescriptions in disciplinary proceedings, although patient identity would not be made public. How many instances the defendant used the computer and patient identity has no relevance to the constitutionality of filing, or the power of the Legislature.

California Bankers Ass'n v. *Shultz, supra,* 416 U.S., at 25-38 discusses the congressional purpose and the "usefulness" of the data collected, not how it will actually be used, if at all. At 30 it notes the lack of any challenge to the authority of the Legislature to treat the subject. Noted at 26, was Congress' extensive study. The same is the case here. *Roe* v. *Ingraham,* 364 F. Supp., at 545. Only an *actual* invasion of constitutionally protected privacy should have been considered, not how defendant administered the program and his results.**

* The only regular computer print-out containing patient identity was the over 30 day and doctor-to-doctor list.

** The fallaciousness of the "proof" that one case revealed by reviewing print-outs shows that the law is unconstitutional (11a) is demonstrated by the obvious fact that if a preliminary injunction had issued there would have been no cases. Or what number of "cases" would have made the statute constitutional?

The plaintiffs conceded (although they now attempt to repudiate this) the constitutionality of the prior law which allowed access to prescriptions by defendants' enforcement agents. 364 F. Supp., at 544. There was no "expectation of privacy" as to prescriptions. Thus there was no question the defendant had the right to have the information—i.e., patient identity, which he is now prohibited from having *via* the filing requirement. On the other hand the decision invalidating reporting continues to allow collection of patient identity by manual means, but not filing and computerization. But given the fiscal resources this is not feasible.*

What the decision below failed to take account of was that the State was not in any way regulating the practice of medicine (which power of regulation cannot be dismissed), but here rather monitoring the traffic in dangerous drugs, a serious health hazard to the public. Practitioners are not prohibited from prescribing Schedule II drugs.** In the area of drugs and their use, public safety has always been superior to private rights, whatever they may be. *Whipple* v. *Martinson,* 256 U.S. 41, 45 (1921); *Robinson* v. *California,* 370 U.S. 660, 664 (1962); see also *Brodsky* v. *Cal. State Board of Pharmacy,* 173 Cal. App. 2d 680, 344 P. 2d 68, 74 (1959); *State* v. *Braun,* 209 Kan. 181, 495 P. 2d 1000, 1004-1005 (1972), cert. denied 409 U.S. 991. When practitioners prescribe and patients receive dangerous drugs, reporting and computerization is reasonable. See *United States* v. *Biswell,* 406 U.S. 311, 316-317 (1972).

There is no support in *Roe* v. *Wade,* 410 U.S. 113 (1973) or *Doe* v. *Bolton,* 410 U.S. 179, 197 (1973), as cited for the opinion below, for the expansive concept that there is a virtually unlimited right to privacy in physician-patient

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* There are only 24 investigators for the whole State (4a-5a).

** The "inhibitions" plaintiffs testified to are simply products of their "fears", not the facts in the record.

matters. Even in *Doe,* the statute, requiring committee review of abortions, "substantially limited" the exercise of a physician's judgment. And ftn. 14 to *Paris Adult Theatre I.* v. *Slaton,* 413 U.S. 49, 66, also referred to "a protected intimate relationship". Only if that relationship already existed, did the "doctor's office" get involved. Quite the contrary, the activity the State in the instant case seeks to monitor, and only after the fact, is use of dangerous drugs. This activity by the State has always been permissible. Also this use may not really be medical. As in *Association of A.P. & S., supra,* the doctor's activities are not beyond review.

Why the plaintiffs should fear more effective monitoring is hard to fathom. The State properly seeks to protect them from unscrupulous practitioners. Their "fears" of misuse had no basis in fact. They were guided by doctors who simply misstated the statute's intent and scope. This continues to the present day. To extend the constitutional right of privacy to filing and computerization of data legitimately available to the State is a serious issue, given the increasing dependence of government on modern data processing in all areas.*

It must be emphasized that the State does not by filing or computerizing triplicate prescription know the patient's illness and the Record will show that the print-outs limited as they are, are usable only by state investigators with access to the complete doctor's file, if necessary. In no way, except by plaintiffs and plaintiffs' doctors injecting utterly false considerations in the prescription process, did patients claim they would, on their personal decisions, reject Schedule II drugs.** This was self-created "harm"

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* Filing is practiced in many areas subject to abuse, *i.e.,* income tax, lawyers' contingent fees, gun-sales, bank-transactions, securities regulation.

** The 125,000 prescriptions processed each month belie any claim medical practice is interfered with. Contrary to appellees' contentions, this does not mean that 125,000 patients went into the computer each month.

and an example of ingenuous pleading. *United States* v. *SCRAP, supra.*

The Legislature determined the need for filing. Whether filing will achieve all the purposes envisioned by the Legislature is not the issue. Whether these hopes are achieved in the end does not affect the law's constitutionality. See *James* v. *Strange,* 407 U.S. 128, 133 (1972); *Mourning* v. *Family Publications Service, Inc.,* 411 U.S. 356, 378 (1973).

The question of the power of the Legislature is not to be confused with the scope of legislative considerations in dealing with the matter of policy. The District Court cannot indulge in a legislative judgment which it obviously did. *Brotherhood of Locomotive Firemen & Enginemen* v. *Chicago R.I. & R. Rd. Co.,* 393 U.S. 129, 136 (1968); see also *Cohen* v. *Beneficial Finance Corp.,* 337 U.S. 541, 548-549 (1949).

Filing and computerization of prescriptions is a modern, effective means to better control misuse and diversion of dangerous drugs. The Constitution does not require that the State choose ineffectual means of fulfilling its duty to protect the public health. *Cf. Rosario* v. *Rockefeller,* 410 U.S. 752, 762, ftn. 10 (1973). It is not for the Courts to determine the level of efficiency of defendant's operation. Or decide how readily the Department of Health can or should uncover irregularities.

Even if the instant legislation had not been the subject of extensive study, which it was, the supposed lack of scientific data would not be a bar to the regulation. As said in *Paris Adult Theatre I.* v. *Slaton, supra,* 413 U.S. at 60; "(i)t is not for us to resolve empirical uncertainties underlying State legislation, save in the exceptional case where that legislation plainly impinges upon rights protected by the Constitution itself." See also *Tyson & Brother* v. *Banton,* 273 U.S. 418, 446 (1927) (dissenting opinion, per Holmes, J.).

Whatever else, it is hardly "plain" that filing of triplicate prescriptions prevents anyone from receiving the medication his doctor desires for him, if that be a constitutional right (cf. *Association of A.P. & S.* v. *Weinberger, supra,* 395 F. Supp. at 134, 135, or that privacy will be invaded by filing of the data (cf. P.H.L. § 3371).

The purpose of the legislation was misstated by the Court below (11a-12a, ftn.) by saying the names on the form will not be of aid in preventing addicts from obtaining drugs by prescription. This ignores the law. P.H.L. § 3380 prohibits the prescribing, administering or dispensing of "controlled substances" to addicts or habitual users except for research, §§ 3324 *et seq.* (Title III) and under specific situations covered in Title V, §§ 3351 *et seq.* The assumption that addicts would not use their own names assumes they will violate another prohibition, P.H.L. § 3397, obtaining drugs (controlled substances) by fraud and deceit. A law cannot be assumed useless because people may violate it. The decision also assumed that the State had no interest in addicts. This is utterly false and a strange assertion. P.H.L. § 3372 requires doctors to report addicts or habitual users of any narcotic drug. Such legislation has been upheld. *Felber* v. *Foote,* 321 F. Supp. 85 (D.Conn. 1970).

The instant appeal has great significances as to the nature of a claim that gives legal standing to sue and the standard of review to be used by a court in examining the basis for legislation. Besides New York, three other states (California, Idaho and Illinois) operate, even now, similar systems. The decision below presents many significant issues warranting review by this Court.

CONCLUSION

For the foregoing reasons probable jurisdiction should be noted and the judgment reversed.

Dated: New York, New York, December 5, 1975.

Respectfully submitted,

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Appendix A, Opinion of Three-Judge Court, Roe v. Ingraham (S.D.N.Y. 73 Civ. 1303).

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

73 Civ. 1303

73 Civ. 1431

RICHARD ROE, an infant by ROBERT ROE, his parent; JOHN DOE, an infant by MARY DOE, his parent; JAMES MOE, an infant by MICHAEL MOE, his parent; JANE POE, MATTHEW T. BRODY, ISRAEL L. SCHMIERER, and EMPIRE STATE PHYSICIANS GUILD, INC.,

Plaintiffs,

against

HOLLIS S. INGRAHAM, as Commissioner of the State of New York Health Department,

Defendant,

GEORGE PATIENT, MARTHA PATIENT, GERALD L. LUSTIG, and THE AMERICAN FEDERATION OF PHYSICIANS AND DENTISTS,

Intervenors.

BEFORE:

HONORABLE WILFRED FEINBERG
United States Circuit Judge

HONORABLE INZER B. WYATT
United States District Judge

HONORABLE ROBERT L. CARTER
United States District Judge

OPINION

CARTER, District Judge

Status of Proceedings

This challenge to the constitutional validity of the New York Public Health Law, § 3300 et seq., pursuant to which under §§ 3331(6), 3332(a) and 3334(4) all prescriptions containing Schedule II substances must be filed with the Bureau of Controlled Substances, Licensing and Evaluation (BCSLE) in Albany on forms supplied by the state is before us on the merits. Plaintiffs seek to enjoin permanently so much of the statutory provisions under attack as require that the names of recipients of Schedule II drugs prescribed by licensed physicians as medications be filed with the state for computerization.

Since the history of the litigation has been set out in our prior opinion, reported at 364 F. Supp. 536, where we denied plaintiffs' motion for a preliminary injunction and defendant's motion to dismiss, we will advert only briefly to the background facts. In 1970 a Temporary New York State Commission to Evaluate the Drugs Laws was created. Its function was to recommend whatever modifications in the law were deemed necessary to meet existing problems in respect of drug abuse. In the Commission's Interim Report drugs were grouped into five schedules. Schedule II drugs (which are the concern of this litigation) recognizably have legitimate and worthwhile uses in the treatment of illnesses and disorders. (*Id.* at P. 10a). Among the Schedule II drugs in this category are, e.g., ritalin, codeine, percodan, morphine and hycodan. These drugs are useful in ameliorating pain, in the treatment of epilepsy, narcolepsy, hyperkinesia, schizoaffective disorders, and migraine headaches, but they also have a high potential for abuse. The legislation before us seeks to prohibit Schedule II legitimate drug medications from being diverted to illegal uses by

governmental oversight of the prescription, distribution and use of these drugs.

In our prior opinion we said that "[p]laintiffs' claims . . . raise novel and serious questions with potentially far reaching consequences as to the permissible reach of the protection afforded by the right of privacy as an independent constitutional guarantee," 364 F. Supp. at 544, and in refusing to dismiss the action we stated that "plaintiffs must be afforded the opportunity to demonstrate that the computerization of names is not necessary for the accomplishment of the state goals, that the controls developed by the state are inadequate to protect against unauthorized disclosure of the computerized information, and that injury to the plaintiffs resulting from the implementation of this system of centralized filing is sufficiently serious to overcome any competing state interest." *Id.* at 546-547.

Findings of Fact

The evidentiary facts relevant to decision on the merits were presented to us in four forms (1) by stipulated facts, (2) depositions taken on December 4 and 6, 1974, (3) exhibits, and (4) live testimony before the court on December 2, 1974. What follows are our findings of fact.

Special prescription forms are required for all Schedule II drugs, and such forms are sent to all qualified physicians who order them. The forms are serially numbered. A letter from the Commissioner of Health instructs physicians on how to secure and obtain the forms, and lists some of the Schedule II drugs and their trade names. A physician dispensing a Schedule II drug is required to keep one copy of the prescription and to mail the original and other copy to the BCSLE in Albany. When the physician prescribes but does not dispense the drug himself, he is again required to keep one copy of the form, but gives the original and remaining copy to the patient, who takes them to a pharmacist in order to have the prescription filled. The

pharmacist keeps the original and sends the copy to the BCSLE. The prescription form contains the name, address, telephone number and DEA[1] (Drug Enforcement Administration) number of the prescribing physician, the date the prescription was issued, the name, age and address of the patient, the name and amount of the drug prescribed, maximum daily dosage, the signature of the physician, the prescription number issued by the pharmacy, the date the prescription was filled, the NDC (National Drug Code) number of the drug, the DEA number of the pharmacy, and the signature of the dispenser.

The prescription forms are received in the mail room of BCSLE in Albany. Since April 1, 1973, the effective date of the Act, BCSLE has been receiving approximately 100,000 prescription forms per month. The forms are taken unopened to a receiving room where they are opened, coded, put into batches of 100 each and logged. These tasks are performed by approximately nine clerks. The batches are then taken into a "processing room" which is a part of the Office of Electronic Data Processing (OEDP). There the information on the forms is key punched onto a recorder disc and after the disc is filled, the information is put on magnetic tapes, and the disc is erased. The magnetic tapes are kept in drawers of a locked cabinet, but while the information is on the disc recorder, it is not kept under lock.

Dr. Arthur G. Baker, Associate Commissioner of Health for Community Health Services, has overall responsibility for the Schedule II prescription program. The BCSLE and the Bureau of Narcotic Control (BNC) are under his jurisdiction. BNC, directed by John J. Bellizzi, is empowered to investigate violations of the Public Health law and of Schedule II regulations. There are 14 BNC investigators in New York City and two each in Buffalo, Roches-

[1] DEA was formerly the Bureau of Narcotics and Dangerous Drugs (BNDD).

ter, Syracuse, White Plains and Albany. Joseph L. Cannizzaro is the BCSLE director, and his agency, in addition to processing, has responsibility for the retention and security of the forms. OEDA, headed by Joseph Bonacci, though a part of the Dept. of Health, apparently is not under Dr. Baker's jurisdiction but is responsible for processing the information contained on the forms onto computers. Approximately thirty-one employees of the Dept. of Health have access to all computerized information developed through the program.

As of the December, 1974, date of the trial, the program had then been in effective operation for roughly twenty months. The evidence presented by the state discloses that the computerized information is helpful in facilitating the study of the number of prescriptions filled per month by the average physician, and the number dispensed by the pharmacist; it aids in detecting instances of over-prescribing and over-dispensing, in detecting forgeries and counterfeit prescriptions. Thus far the uses derived from having the individual recipient's identity revealed were reported to be: (1) identifying those persons who using their own name go from doctor to doctor to obtain an illicit supply of drugs and (2) uncovering those receiving more than a 30-day supply of Schedule II drugs per month. Two such names have been discovered since the computerized program has been in operation. Both were referred to the BNC for investigation. In one case, the investigation disclosed a bona fide doctor-patient relationship, and in the other the investigation was still open when all evidentiary data was submitted for our consideration.

Testimony was presented by Joseph Jules Wasserman, who specializes in auditing the security and controls of computer systems, the burden of which was to demonstrate the weaknesses in the security system at the BCSLE and OEDP in the processing, computerizing and storing of the information on the prescription forms. Dr. Joseph

Martin Rosenberg, a psychologist, testified that the program had an adverse effect in respect of the doctor-patient relationship and would dissuade individuals who might need Schedule II drugs from undergoing required treatment.

At the hearing before us Michael Moe and Mary Doe expressed concern that their children, who are being treated with ritalin for hyperkinesia, will be stigmatized because the state will have a long file on their children in a narcotics and dangerous drug context. Mrs. Doe testified that she has taken her child off ritalin; the child is not doing well without the medication, but the alternative she feels is to have him branded for life. Jane Poe testified that she had had encephalitis followed by complications resulting in the loss of all control of the eyes so that they move uncontrollably in one direction or the other—an affliction called the oculogyric crisis. When she learned that under the new regulation her name was to go on a computer because the amphetamine with which her condition was treated was a Schedule II drug, she believed she would be labeled a drug addict.

Martha Patient, who suffers from migraine headaches, is treated by a medication containing fiorinal, codeine and cathedot. On learning that her name was to be reported to Albany and put on a computer when prescriptions for her medication were filled, she stopped the medication. Subsequently, however, her headaches returned, and she was forced to resume treatment. She has no confidence that information once put on a computer will remain confidential. George Patient has cancer of the lungs and had three ribs removed. Percodan was prescribed for the pain. When he learned his name would go to Albany, he tried other kinds of medication which did not work. Later he learned that he could get the drug through his union from out of state, and he now follows that course.

Four doctors testified: Mathew Brady, who does not believe any ethical doctor can live with the law; Stanley

Fishman, who testified to a belief that the law's requirement that patients be identified and their name recorded on a computer disc would have an adverse effect on the patient; Israel S. Schmierer, who expressed the view that the law entrenches upon the confidentiality of the patient-doctor relationship; and Gerald Lustig who refuses to prescribe any Schedule II drugs for his private patients. All testified that they felt obligated to advise their patients or a responsible member of their family about the state prescription program for Schedule II drugs, and reported a reaction of shock, fear and concern on the part of their patients on learning that their names would be sent to Albany and put on a computer.

Determination

The justification the State advances for the state prescription program, including identification of the patient being treated with a Schedule II drug, is the grave danger of abuse and consequential psychological dependence use of these drugs may cause. The issue is troublesome. The state seeks to deal with a well-recognized and prevalent evil—the wide-spread proliferation of drug abuse. In seeking through the legislation before us to prevent the diversion of Schedule II drugs to illegal use, the state manifestly is performing a legitimate governmental function. On the other hand plaintiffs assert that the statute in infringing upon the doctor-patient relationship intrudes on one of the zones of privacy accorded constitutional protection. If the plaintiffs' claims have validity, they are asserting rights which are at the core of "those liberties of the individual which history has attested as the indispensable conditions of an open as against a closed society [and those claims, therefore, are entitled to] respect lacking when appeal is made to liberties which derive merely from shifting economic arrangements." *Kovacs* v. *Cooper,* 336 U.S. 77, 89, 95 (1949) (Frankfurter, J. Concurring). *See also Griswold* v. *Connecticut,* 381 U.S. 479, 482-485

(1965); *Id.* at 486, 487-497 (Goldberg, J., concurring); *Id.* at 502, 503 (White, J., concurring).

Although the focus on privacy as a separate and distinct guarantee is of recent origin, *see Griswold* v. *Connecticut, supra; Eisenstadt* v. *Baird,* 405 U.S. 438 (1972); *Roe* v. *Wade,* 410 U.S. 113 (1973); *Doe* v. *Bolton,* 410 U.S. 179 (1973), Justice Blackmun, speaking for a majority of the Court, traced the right of privacy to "a line of decisions . . . going back perhaps as far as *Union Pacific R. Co.* v. *Botsford,* 141 U.S. 250, 251 (1891) [that] has recognized that a right of personal privacy, or a guarantee of certain areas or zones of privacy" are given constitutional protection. *Roe* v. *Wade, supra,* at 152. It was pointed out that the right of privacy had been said to rest on the First Amendment, *Stanley* v. *Georgia,* 394 U.S. 557, 564 (1969); the Fourth and Fifth Amendments; *Terry* v. *Ohio,* 392 U.S. 1, 8-9 (1968); *Katz* v. *United States,* 389 U.S. 347, 350 (1967); the penumbras of the Bill of Rights, *Griswold* v. *Connecticut, supra,* at 484-485; on the Ninth Amendment, *Id.* at 486 (Goldberg, J. concurring), and on the concept of liberty guaranteed by the Fourteenth Amendment, *Meyer* v. *Nebraska,* 262 U.S. 390, 399 (1923). *Ibid.* Only those rights basic to a free society or which are encapsulated within the concept of ordered liberty are included in the constitutional guarantee of privacy. Cited in precedential support for the conclusion that the right of privacy is of constitutional dimensions were *Eisenstadt* v. *Baird, supra,* at 453, 454; *Loving* v. *Virginia,* 388 U.S. 1, 12 (1967); *Prince* v. *Massachusetts,* 321 U.S. 158, 166 (1944); *Skinner* v. *Oklahoma,* 316 U.S. 535, 541-542 (1942); *Pierce* v. *Society of Sisters,* 268 U.S. 510, 535 (1925); and *Meyer* v. *Nebraska,* 262 U.S. 390, 399 (1923). The short description of each of these cases gives an expanded reading of the zone of privacy protected. *Id.* at 152-153.

By the very nature of our society which distinguishes the spiritual from the profane, church from state, inherent and inalienable rights from those rights that govern-

ment may give or withhold, *a fortiori* a concept of privacy must inevitably emerge. Konvitz, *Privacy and the Law: A Philosophical Prelude,* 31 Law & Contemp. Prob. 272, 273 (1966). The concept of privacy is an affirmation of the importance of certain aspects of the individual and his desired freedom from needless outside interference. It is sometimes described as a sphere of space that a man may carry with him which is protected from unwarranted outside intrusion, as the right of selected disclosures about oneself and as a right of personal autonomy. Henkin, *Privacy and Autonomy,* 74 Colum. L. Rev. 1410 (1974). Konvitz, *supra.*

"[I]t is apparent [therefore] *that* the right of privacy is constitutionally protected. It is *when* and *how* which create the problems." *Roberts* v. *Clement,* 252 F. Supp. 835, 845, 848 (E.D. Tenn. 1966) (Darr, J. concurring) (emphasis in the original); Kauper, *Penumbras, Peripheries, Emanations, Things Fundamental and Things Forgotten: The Griswold Case,* 64 Mich. L. Rev. 235 (1965); Parker, *A Definition of Privacy,* 27 Rut. L. Rev. 275 (1974); Gross, *The Concept of Privacy,* 42 NYU L. Rev. 34 (1967); Note, 26 Stan. L. Rev. 1161 (1974); Note, 48 NYU L. Rev. 670 (1973). Our task, however, has been simplified since we read *Roe* v. *Wade,* as holding implicitly and *Doe* v. *Bolton,* 410 U.S. at 197 (1973), as holding explicitly that the doctor-patient relationship is one of the zones of privacy accorded constitutional protection. Justice Douglas has described the expectation of privacy in the doctor-patient relationship as being exceeded only by that expectation in the relationship of a penitent to his priest. *Id.* at 219. *Paris Adult Theatre I.* v. *Slaton,* 413 U.S. 49 (1973), reaffirmed the holding in *Roe* and *Doe* that privacy embraced the doctor-patient relationship. There it was said, at page 66, note 13: "the constitutionally protected privacy of family, marriage, motherhood, procreation and child rearing is not just concerned with a particular place, but with a protected intimate relationship. Such protected privacy extends to the doc-

tor's office, the hospital, the hotel room, or as otherwise required to safeguard the right to intimacy involved." While the doctor-patient relationship involved in *Roe* and *Doe* concerned the most intimate personal relationships, sexual relations and "whether to bear or beget a child," *Eisenstadt* v. *Baird, supra,* at 453, and the right of privacy has primarily focused on home and family, it would be too restricted a reading of precedent for us to hold that the physician-patient relationship here is not constitutionally protected merely because it does not concern medical advice or professional judgments concerning child bearing. *See Roe* v. *Ingraham,* 480 F. 2d 102, 107 (2d Cir. 1973).

An individual's physicial ills and disabilities, the medication he takes, the frequency of his medical consultation are among the most sensitive of personal and psychological sensibilities. One does not normally expect to be required to have to reveal to a government source, at least in our society, these facets of one's life. Indeed, generally one is wont to feel that this is nobody's business but his doctor's and his pharmacist's. When these physical illnesses and disabilities require as here treatment by drugs which, in light of the current epidemic of drug abuse in the society, are under governmental control and regulation, there is legitimate concern that information that one, one's children or an intimate is under treatment with such drugs not be broadcast to unauthorized sources. There is fear that the adults or children will be stigmatized if their use of the drug becomes known. There is no question but that the statutory requirement challenged here intrudes upon and interferes with the doctor-patient relationship.

Even though the right of privacy which we find to exist in the doctor-patient relationship at issue in this case is constitutionally protected, it is equally clear that the right has limitations. When the state interest asserted is compelling, the right of privacy may be impinged upon, but "a governmental purpose to control or prevent activities

constitutionally subject to state regulation may not be achieved by means which sweep unnecessarily broadly and thereby invade the area of protected freedoms," *NAACP* v. *Alabama,* 377 U.S. 288, 307 (1964); *Erznoznik* v. *City of Jacksonville,* —— U.S. ——, 42 L.W. 4809, 4813 (decided June 24, 1975); *Shelton* v. *Tucker,* 364 U.S. 479, 488 (1960); *Cantwell* v. *Connecticut,* 310 U.S. 296, 304 (1940); where fundamental rights are involved, "[p]recision of regulation must be the touchstone." *NAACP* v. *Button,* 371 U.S. 415, 438 (1963).

Concededly the state effort to control drug abuse and to prevent illicit trafficking in dangerous drugs fosters a legitimate state purpose, and ordinarily we would be reluctant to interfere. The regulatory scheme, however, has a needlessly broad sweep. The state prescription form program provides for issuing serially numbered prescription forms to physicians. Each doctor prescribing and each pharmacist dispensing any Schedule II drugs are given a DEA number. They, therefore, are readily identifiable. The state can promptly determine the quantity of drugs prescribed and dispensed by particular physicians and pharmacists. Over-prescribing or dispensing, forgeries and thefts can be detected. Having the name of the person receiving the drugs on the state's form adds nothing. Indeed, admittedly the only purpose this information serves is to identify individual patients who without using an alias go from doctor to doctor to secure Schedule II drugs and those individuals who secure more than a 30-day supply in any single month. During the 20-month life of the program only one such unresolved incident in this category had been unearthed. The diminution of a constitutionally guaranteed freedom is too great a price to pay for such a small governmental yield.[2]

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[2] There is no state claim that the names on the form will be of aid in preventing addicts from access to drugs by prescription. They,

(*footnote continued on following page*)

The state argues that it is doing no more than it did under the old regulations when prescriptions with the patient's name were required to be kept by pharmacists for inspection. That argument must be rejected. The intrusion here is not only more immediate, its impact is greater. A name on a prescription in the files of one of many thousands of pharmacists in the state of New York is entirely different from one's name on a form in Albany which is transferred to computerized records and stored for instant retrieval.

We are reinforced in the belief that the right of privacy covers the situation of the doctor-patient relationship involved in this case by the Supreme Court's decision in another area. In *California Bankers Ass'n* v. *Shultz,* 416 U.S. 21 (1974), the concurring (*Id.* at 78) and dissenting (*Id.* at 79, 91, 93) opinions which secured adherence from a majority of the Court, made clear that if the regulations or the statute had been read as an unrestricted requirement that all bank transactions of whatever dimension be reported, the Bank Secrecy Act would have been held to have been an invalid intrusion upon the "legitimate expectations of privacy," of rank and file depositors. (Powell, J. concurring, 416 U.S. at 79). What saved the act from condemnation was the view of Justices Powell and Blackmun that the restricted reach of the reporting requirement made the intrusion sufficiently discrete that it did not entrench unwarrantedly upon the zone of privacy.

(*footnote continued from preceding page*)

of course, would not use their own name or the same name in going from doctor to doctor. The doctors who testified before us all stated, without being controverted, that they could readily recognize an addict who came to their office seeking a drug by prescription, because they would ask for a specific drug and be vague about their illness and the name of their physician who had prescribed the medication initially. Moreover, the program is not designed to ferret out addicts in any case.

Accordingly, we hold that so much of the New York Health Law as requires reporting to state authorities in Albany the names and addresses of patients who receive Schedule II drugs as medication prescribed by duly licensed physicians is an unconstitutional interference with plaintiffs' rights of privacy guaranteed under the Fourteenth Amendment. The bases for our decision make unnecessary an evaluation of the operative state measures to insure confidentiality.

SETTLE ORDER ON NOTICE.

Dated: New York, New York, August 13, 1975.

WILFRED FEINBERG
Circuit Judge

INZER B. WYATT
District Judge

ROBERT L. CARTER
District Judge

Appendix B, Judgment Appealed From.

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

73 Civ. 1303

73 Civ. 1431

RICHARD ROE, an infant by ROBERT ROE, his parent; JOHN DOE, an infant by MARY DOE, his parent; JAMES MOE, an infant by MICHAEL MOE, his parent; JANE POE, MATTHEW T. BRODY, ISRAEL L. SCHMIERER, and EMPIRE STATE PHYSICIANS GUILD, INC.,

Plaintiffs,

against

ROBERT P. WHALEN, as Commissioner of Health of the State of New York,

Defendant,

GEORGE PATIENT, MARTHA PATIENT, GERALD L. LUSTIG, and THE AMERICAN FEDERATION OF PHYSICIANS AND DENTISTS,

Intervenors.

Plaintiffs above named having filed a complaint for a declaratory judgment and an injunction in this matter and Intervenors having thereafter also filed such a complaint and the two matters having been consolidated for discovery and trial; and the parties having submitted (1) a stipulation of facts set forth in the pretrial order made herein on November 18, 1974 and (2) evidence (testimony and exhibits) in deposition form pursuant to the pretrial order made herein on November 21, 1974; and the Court having considered such stipulation of facts and evidence and the

evidence presented at trial held herein on December 2, 1974; and after due deliberation, the Court having rendered its decision herein by opinion filed on August 13, 1975; and this Court having made an order on October 2, 1975 pursuant to F.R.Civ.P. 25(d) substituting the present Commissioner of Health of the State of New York, Robert P. Whalen, as the defendant herein, for his predecessor Hollis S. Ingraham:

Now, therefore, on all prior proceedings and on the record herein, IT IS ORDERED, ADJUDGED AND DECREED THAT

1. Sections 3331(6), 3332(2)(a) and 3333(4) of the New York Public Health law insofar as they require disclosure to the State of New York of the identity of patients receiving prescriptions for Schedule II controlled substances be, and hereby are, declared to be an unconstitutional interference with plaintiffs' rights of privacy guaranteed under the Fourteenth Amendment of the United States Constitution.

2. Defendant Robert P. Whalen, Commissioner of Health of the State of New York, his agents, servants and employees be, and hereby are, enjoined and restrained from (a) enforcing those provisions of Sections 3331(6), 3332(2)(a) and 3333(4) of the New York Public Health law which require disclosure to the State of New York of the identity of patients receiving Schedule II controlled substances; (b) accepting for filing prescription forms (or copies thereof) or any other documents disclosing the identities of patients receiving prescriptions for Schedule II controlled substances; and (c) requiring physicians or pharmacists to complete and file with any agency of the State of New York any prescription forms (or copies thereof) disclosing the identity of patients receiving prescriptions for Schedule II controlled substances.

3. Defendant Robert P. Whalen, Commissioner of Health of the State of New York, shall, within 60 days from the date hereof, (a) cause to be destroyed all New York State prescription forms previously filed with the New York State Department of Health containing the identities of patients receiving prescriptions for Schedule II controlled substances; and (b) cause to be expunged patients' names on all records made from the New York State prescription forms, including but not limited to computer tapes and discs.

4. Within 14 days after the destruction of records and expungement of patients' names required by paragraph "3" hereinabove, defendant Robert P. Whalen, Commissioner of Health of the State of New York, shall cause to be filed an affidavit in this matter, describing the time, place and manner of such destruction and expungement and containing an itemization of all records destroyed and of all records on which the patients' names have been expunged.

5. Paragraphs "3" and "4" of this judgment are stayed on condition that defendant timely file a notice of appeal to the United States Supreme Court as provided by law, and such stay shall continue until disposition of the appeal or until further order of the Supreme Court. During the pendency of the stay provided herein, defendant shall maintain all New York State triplicate prescription forms or records made therefrom containing the identities of patients receiving Schedule II controlled substances in a sealed vault or other equally secure place and is enjoined from adding any patients' names to the computer discs and tapes under defendant's control or otherwise making from the New York State triplicate prescription forms any record containing the name of a patient receiving Schedule II controlled substances.

6. Jurisdiction is hereby retained by the Court for the purpose of entering such further orders as may be necessary or appropriate to effectuate the terms of this final order and judgment.

Dated: New York, New York
October 9, 1975

WILFRED FEINBERG
United States Circuit Judge

INZER B. WYATT
United States District Judge

ROBERT L. CARTER
United States District Judge

JUDGMENT ENTERED—10/9/75

RAYMOND F. BURGHARDT
Clerk

Appendix C, Notice of Appeal (Filed October 20, 1975).

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

73 Civ. 1303
73 Civ. 1431
(RLC)

RICHARD ROE, an infant by ROBERT ROE, his parent; JOHN DOE, an infant by MARY DOE, his parent; JAMES MOE, an infant by MICHAEL MOE, his parent; JANE POE, MATTHEW T. BORDY, ISRAEL L. SCHMIERER and EMPIRE STATE PHYSICIANS GUILD, INC.,

Plaintiffs,

against

ROBERT P. WHALEN, as Commissioner of Health of the State of New York,

Defendant,

and

GEORGE PATIENT, MARTHA PATIENT, GERALD L. LUSTIG, and THE AMERICAN FEDERATION OF PHYSICIANS AND DENTISTS,

Intervenors.

SIRS:

PLEASE TAKE NOTICE that pursuant to 28 U.S.C. § 1253, the defendant Robert P. Whalen, as substituted for the original defendant Hollis S. Ingraham, hereby appeals to the United States Supreme Court from a final judgment and order of a statutory three-judge District Court entered in the United States District Court for the Southern District of New York on October 9, 1975, and this appeal is taken from each and every part of the final order and judgment except that portion of the fifth ("5") decretal paragraph, which grants a stay of paragraphs "3" and "4", namely the first sentence of "5", which is conditioned on

timely filing of this notice of appeal; this appeal is taken from the second sentence in paragraph "5".

Dated: New York, New York, October 17, 1975.

Yours, etc.,

LOUIS J. LEFKOWITZ
Attorney General of the
State of New York
Attorney for defendant
By

s/
A. SETH GREENWALD
Assistant Attorney General
Office & P.O. Address
Two World Trade Center
New York, New York 10047
Tel. (212) 488-3396

To: CLERK

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
Foley Square
New York, New York 10007

SHEA GOULD CLIMENKO KRAMER
& CASEY (and SOLOMON Z. FERZIGER)
330 Madison Avenue
New York, New York 10017

NORWICH RAGGIO & JAFFE
Two Pennsylvania Plaza
New York, New York 10001

Appendix D, Article 33, Public Health Law (Pertinent Portions).

TITLE I—GENERAL PROVISIONS (in part)

• • •

§ 3304. Prohibited acts

It shall be unlawful for any person to manufacture, sell, prescribe, distribute, dispense, administer, possess, have under his control, abandon, or transport a controlled substance except as expressly allowed by this article.

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§ 3306. Schedules of controlled substances

There are hereby established five schedules of controlled substances, to be known as schedule I, II, III, IV and V respectively. Such schedules shall consist of the following substances by whatever name or chemical designation known:

• • •

SCHEDULE II

(a) Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate.

(2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (1), except that these substances shall not include the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) Coca leaves and any salt, compound, derivative,

or preparation of coca leaves, and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine.

(b) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Alphaprodine.
(2) Anileridine.
(3) Bezitramide.
(4) Dihydrocodeine.
(5) Diphenoxylate.
(6) Fentanyl.
(7) Isomethadone.
(8) Levomethorphan.
(9) Levorphanol.
(10) Metazocine
(11) Methadone.
(12) Methadone-Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane.
(13) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid.
(14) Pethidine.
(15) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine.
(16) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate.
(17) Pethidine-Intermediate-C, 1 methyl-4-phenylpiperidine-4-carboxylic acid.
(18) Phenazocine.
(19) Piminodine.
(20) Racemethorphan.

(21) Racemorphan.

(22) Etorphine hydrochloride.

(c) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a potential for abuse associated with a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers;

(2) Phenmetrazine and its salts;

(3) Any substance which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers;

(4) Methylphenidate.

(d) Unless specifically excepted or unless listed in another schedule, methaqualone or any salts, isomers or salts of isomers of methaqualone.

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TITLE IV—DISPENSING TO ULTIMATE USERS

§ 3330. Schedule I substances

No prescription may be made or filled for any controlled substance in schedule I nor may such substance be possessed, distributed, dispensed or administered except pursuant to title III of this article.

§ 3331. Scheduled substances administering and dispensing by practitioners

1. Except as provided in titles III or V of this article, no substance in schedules II, III, IV, or V may be prescribed for or dispensed or administered to an addict or habitual user.

2. A practitioner, in good faith, and in the course of his professional practice only, may prescribe, administer and dispense substances listed in schedules II, III, IV, and V, or he may cause the same to be administered by a designated agent under his direction and supervision.

3. A veterinarian, in good faith, and in the course of the practice of veterinary medicine only, may prescribe, administer and dispense substances listed in schedules II, III, IV, and V or he may cause them to be administered by a designated agent under his direction and supervision.

4. No such substance may be dispensed unless it is enclosed within a suitable and durable container upon which is indelibly typed, printed or otherwise legibly written upon an orange label affixed to such container in a manner which would inhibit its removal, the following:

(a) the name and address of the ultimate user for whom the substance is intended, or, if intended for use upon an animal, the species of such animal and the name and address of the owner or person in custody of such animal;

(b) the name, address, and telephone number of the dispensing practitioner;

(c) specific lirections for use, including but not limited to the dosage and frequency of dosage, and the maximum daily dosage;

(d) the legend, prominently marked or printed in either boldface or upper case lettering: "CONTROLLED SUBSTANCE, DANGEROUS UNLESS USED AS DIRECTED";

(e) the date of dispensing;

(f) either the name of the substance or such code number assigned by the department for the particular substance pursuant to section thirty-three hundred eighteen of this article.

5. No more than a thirty day supply or, pursuant to regulations of the commissioner enumerating conditions warranting specified greater supplies, no more than a three month supply of a schedule II, III or IV substance, as determined by the directed dosage and frequency of dosage, may be dispensed by an authorized practitioner at one time.

6. A practitioner dispensing a substance which may be prescribed only upon an official New York state prescription must at the time of such dispensing prepare an official New

York state prescription in the manner set forth in subdivision two of section thirty-three hundred thirty-two of this article. The practitioner shall retain one copy for five years and shall file the original and one copy with the department by not later than the fifteenth day of the next month following the month in which the substance was delivered. This requirement shall not apply to the dispensing by a practitioner pursuant to section thirty-three hundred fifty-two of this article. (emphasis supplied and following)

§ 3332. Making of official New York state prescriptions for scheduled substances

1. No substance for which an official New York state prescription is required may be prescribed by a practitioner except on an official New York state prescription, and in good faith and in the course of his professional practice only.

2. Such prescription shall be prepared in triplicate, written with ink, indelible pencil or, apart from the practitioner's signature, typewriter. The original and both copies must contain the follow:

(a) the name, address, and age of the ultimate user for whom the substance is intended, or, if the ultimate user is an animal, the species of such animal and the name and address of the owner or person in custody of such animal;

(b) the name, address, registration number, telephone number, and handwritten signature of the prescribing practitioner;

(c) specific directions for use, including but not limited to the dosage and frequency of dosage and the maximum daily dosage;

(d) the date upon which such prescription was actually signed by the prescribing practitioner.

3. No such prescription shall be made for a quantity of substances which would exceed a thirty day supply or, pursuant to regulations of the commissioner enumerating conditions warranting specified greater supplies, for a quantity

of substances which would exceed a three month supply, if the substance were used in accordance with the directions for use.

4. The practitioner shall retain one copy of such prescription for five years and shall deliver the original and one copy to the ultimate user.

§ 3333. Dispensing upon official New York state prescription

1. A licensed pharmacist may, in good faith, and in the course of his professional practice, sell and dispense to an ultimate user controlled substances for which an official New York state prescription is required only upon the delivery to such pharmacist, within thirty days of the date such prescription was signed by an authorized practitioner, of the original and one copy of such official New York state prescription.

2. No such substance may be so dispensed or sold unless it is enclosed within a suitable and durable container and affixed to such container in a manner which would inhibit its removal is an orange label upon which is indelibly typed, printed, or otherwise legibly written:

(a) the name and address of the ultimate user for whom the substance is intended, or if intended for use upon an animal, the species of such animal and the name and address of the owner or person in custody of such animal;

(b) the name, address, and telephone number of the pharmacy from which such substance is dispensed;

(e) specific directions for use as stated on the prescription;

(d) the name of the prescribing practitioner;

(e) the legend, prominently marked or printed in either boldface or upper case lettering: "CONTROLLED SUBSTANCE, DANGEROUS UNLESS USED AS DIRECTED";

(f) the number of the prescription under which it is recorded in the pharmacist's prescription file;

(g) the date of filling; and

(h) such code number assigned by the department for the particular substance pursuant to section thirty-three hundred eighteen of this article, or when requested by the practitioner, the name of such substance.

3. The pharmacist filling the prescription shall endorse upon the original and copy thereof the date of delivery, his signature, and the registration number of the pharmacy.

4. The endorsed original prescription shall be retained by the proprietor of the pharmacy for a period of five years. The endorsed copy of such prescription shall be filed with the department by not later than the fifteenth day of the next month following the month in which the substance was delivered.

§ 3334. Emergency oral prescriptions for schedule II drugs

1. In an emergency situation, as defined by rule or regulation of the department, a practitioner may orally prescribe and a pharmacist may dispense to an ultimate user controlled substances in schedule II; provided however the pharmacist shall:

(a) contemporaneously reduce such prescription to writing;

(b) dispense the substance in conformity with the labeling requirements applicable to the type of prescription which would be required but for the emergency; and

(c) make a good faith effort to verify the practitioner's identity, if the practioner is unknown to the pharmacist.

2. No oral prescription shall be filled for a quantity of controlled substances which would exceed a five day supply if the substance were used in accordance with the directions for use.

3. Within seventy-two hours after authorizing an emergency oral prescription, the prescribing practitioner shall cause to be delivered to the pharmacist the original and

one copy of an official New York state prescription. Such prescription shall, in addition to the information otherwise required, also have written or typed upon its face the words: "Authorization for emergency dispensing." If the pharmacist fails to receive such prescription he shall notify the department in writing within seven days from the date of dispensing the substance.

4. Such official New York state prescription shall be endorsed, retained and filed in the same manner as is otherwise required for such prescriptions.

§ 3335. Making of written prescriptions for controlled substances

1. Except as provided in section thirty-three hundred thirty-seven, substances in schedules III, IV and V for which an official New York state prescription is not required, may be prescribed by a practitioner only on a written prescription made in good faith and in the course of his professional practice.

2. Such written prescription shall be prepared in the same manner and contain the same information as is required by subsection two of section thirty-three hundred thirty-two of this article, except that an official New York state prescription need not be used and the practitioner need not prepare, deliver or retain copies of the prescription.

3. No such prescription shall be made for a quantity of substances which would exceed a thirty day supply or, pursuant to regulations of the commissioner enumerating conditions warranting specified greater supplies, for a quantity of substances which would exceed a three month supply, if the substance were used in accordance with the directions for use.

§ 3336. Dispensing upon written prescription

1. A licensed pharmacist may, in good faith and in the course of his professional practice, dispense to an ultimate

user controlled substances in schedules III, IV, or V for which an official New York state prescription is not required, upon delivery to such pharmacist of a written prescription within thirty days of the date such prescription was signed by an authorized practitioner.

2. Such substance may be dispensed only if packaged and labeled in conformity with the provisions of subsection two of section thirty-three hundred thirty-three of this article.

3. The pharmacist filling the written prescription shall endorse his signature and the date of delivery to the ultimate user. Such endorsed prescription shall be retained by the proprietor of the pharmacy for a period of five years.

§ 3337. Oral prescriptions schedule III, IV and V substances

1. A practitioner may orally prescribe and a pharmacist may dispense to an ultimate user controlled substances in schedules III, IV or V for which an official New York state prescription is not required; provided however the pharmacist shall:

(a) contemporaneously reduce such prescription to writing;

(b) dispense the substance in conformity with the labeling requirements applicable to a written prescription; and

(c) make a good faith effort to verify the practitioner's identity, if the practioner is unknown to the pharmacist.

2. No oral prescription shall be filled for a quantity of controlled substances which would exceed a five day supply if the substance were used in accordance with the directions for use, except that with respect to a schedule IV substance such prescription shall not exceed a thirty-day supply or one hundred dosage units, whichever is less.

3. Within seventy-two hours after authorizing such an oral prescription, the prescribing practitioner shall cause to be delivered to the pharmacist a written prescription.

If the pharmacist fails to receive such prescription he shall make a record of such fact in such manner and detail as the commissioner, by regulation, shall require.

4. Such written prescription shall be endorsed, retained and filed in the same manner as is otherwise required for such prescriptions.

Added L.1972, c. 878, § 2; amended L.1974, c. 960, § 1; L.1974, c. 961, § 1; L.1974, c. 965, § 13.

§ 3338. Official New York state prescription forms

1. Official New York state prescription forms shall be prepared and issued by the department in groups of one hundred forms, each form in triplicate and serially numbered. Such forms shall be furnished at a cost of ten dollars per group of one hundred forms to practitioners authorized to write such prescriptions and to institutional dispensers. Such prescription blanks shall not be transferable.

2. Except as expressly authorized by section thirty-three hundred thirty-four, substances listed in schedule II may be prescribed or dispensed only upon an official New York state prescription.

3. The commissioner may, by rule or regulation, require that a particular substance in schedule III or schedule IV, or particular preparations containing such substance, be prescribed or dispensed upon an official New York state prescription.

4. The commissioner is hereby authorized and empowered to make rules and regulations, not inconsistent with this article, with respect to the retention or filing of such forms, the maximum number of forms which may be issued at any one time, the period of time after issuance by the department that such form shall remain valid for use, and the manner in which practitioners associated with institutional dispensers may use such forms, or any other matter of procedure or detail necessary to effectuate or clarify the provisions of this section and to secure

proper and effective enforcement of the provisions of this article.

5. Upon a finding by the commissioner that a person has wilfully failed to comply with the provisions of this article, the commissioner may revoke, cancel or withhold official New York state prescription forms which have been issued or for which application has been made.

§ 3339. Refilling of prescriptions for controlled substances

1. An official New York state prescription may not be refilled.

2. A written prescription may be refilled not more than the number of times specifically authorized by the prescriber upon the prescription, provided however no such authorization shall be effective for a period greater than six months from the date the prescription is signed. In the event that the prescription authorizes the dispensing of more than a thirty day supply of schedule III, schedule IV or schedule V substances pursuant to regulations of the commissioner enumerating conditions warranting specified greater supplies, the prescription may be refilled only once.

3. Unless an earlier refilling is authorized by the prescriber, no written prescription may be refilled earlier than seven days prior to the date the previously dispensed supply would be exhausted if used in conformity with the directions for use.

§ 3341. Institutional dispensers certificates of approval

1. No institutional dispenser as herein before defined, shall receive, possess or cause controlled substances to be administered or dispensed without first having been issued a certificate of approval authorizing such activity by the commissioner.

2. Upon application of an institutional dispenser for a certificate of approval, the commissioner shall issue such certificate if he is satisfied that:

(a) the applicant and its managing officers are of good moral character;

(b) the applicant possesses the necessary land, building, paraphernalia and staffs to properly carry on the activities described in the application;

(c) the applicant will be able to maintain effective control against diversion of controlled substances; and

(d) the applicant will be able to comply with all applicable state and federal laws.

3. Institutional dispenser to whom such certificates have been issued shall thereafter register biennially with the department. The fee for such certificate and for each biennial registration shall be twenty-five dollars.

4. Certificates and registrations issued under this section shall be effective only for and shall specify:

(a) the name and address of the institutional dispenser;

(b) the nature of the controlled substance, or substances, either by name or schedule, or both, for which the certificate or registration is issued.

§ 3342. Dispensing and administering by institutional dispensers

1. An institutional dispenser may cause controlled substances to be administered or dispensed for use on its premises or for the immedite care or treatment of a patient lawfully being transferred in an emergency situation, as defined by rule or regulation of the commissioner, to an alternative medical facility only pursuant to a written order by a practitioner for medication. Such orders shall be made and preserved in the manner and form as the commissioner shall, by regulation, prescribe.

2. An institutional dispenser may dispense controlled substances for use off its premises only pursuant to a prescription, prepared and filed in conformity with this title.

3. An institutional dispenser shall maintain records of all controlled substances dispensed and administered in such manner as the commissioner shall, by regulation, require.

§ 3343. Reports and records

1. Prescriptions and copies of prescriptions shall be preserved in the following manner:

(a) prescribing practitioners and dispensing practitioners shall preserve the retained copy of an official New York state prescription in a separate file maintained exclusively for such records;

(b) pharmacists dispensing controlled substances upon prescription shall preserve such prescriptions in such manner as the commissioner shall, by regulation, require.

2. Practitioners and pharmacies shall maintain records of all controlled substances received and dispensed in such manner as the commissioner shall, by regulation, require.

§ 3345. Possession of controlled substances by ultimate users original container

Except for the purpose of current use by the person or animal for whom such substance was prescribed or dispensed, it shall be unlawful for an ultimate user of controlled substances to possess such substance outside of the original container in which it was dispensed.

Violation of this provision shall be an offense punishable by a fine of not more than fifty dollars.

TITLE V—DISPENSING TO ADDICTS AND HABITUAL USERS (in part)

§ 3350. Dispensing prohibition

Controlled substances may not be prescribed for, or administered or dispensed to addicts or habitual users of

controlled substances, except as provided by this title or title III.

§ 3351. Dispensing for medical use

1. Controlled substances may be prescribed for, or administered or dispensed to an addict or habitual user:

(a) during emergency medical treatment unrelated to abuse of controlled substances;

(b) who is a bona fide patient suffering from an incurable and fatal disease such as cancer or advanced tuberculosis;

(c) who is aged, infirm, or suffering from serious injury or illness and the withdrawal from controlled substances would endanger the life or impede or inhibit the recovery of such person.

2. Controlled substances may be ordered for use by an addict or habitual user by a practitioner and administered by a practitioner or registered nurse to relieve acute withdrawal symptoms.

3. Methadone, or such other controlled substance designated by the commissioner as appropriate for such use, may be ordered for use of an addict by a practitioner and dispensed or administered by a practitioner or his designated agent as interim treatment for an addict on a waiting list for admission to an authorized maintenance program.

4. Methadone, or such other controlled substance designated by the commissioner as appropriate for such use, may be administered to an addict by a practitioner or by his designated agent acting under the direction and supervision of a practitioner, as part of a regime designed and intended to withdraw a patient from addiction to controlled substances.

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§ 3356. Central registry confidentiality

1. The department shall establish or cause to be established a central registry as part of which the following information shall be assembled:

(a) the name and other identifying data relating to each reported addict;

(b) the status of each addict awaiting admission to an approved program or programs;

(c) the status of each addict in an approved program.

2. Identifying data in such registry with respect to an individual addict shall be available only to:

(a) a practitioner attempting to ascertain the status of an addict seeking treatment with him or admission to a program with which he is associated;

(b) an agency, department of government, or commission established pursuant to the mental hygiene law and authorized to gather such information.

TITLE VI—RECORDS AND REPORTS

§ 3370. Preserving and inspection of records

1. Any record, including prescriptions, required to be kept or maintained by this article shall be preserved for a period of at least five years following the date of the event or transaction recorded, unless a shorter period of time is specifically provided.

2. Such records shall be made available during business hours for inspection and copying by any officer or employee of the department who is charged with the enforcement of this article and to any officer or employee of this state charged with the duty of regulating or licensing of any person who by virtue of such license is authorized to obtain, distribute, dispense or administer controlled substances.

3. [See, also, subd. 3 below] Every record, including prescriptions, required to be kept under this article shall

be maintained at the premises where the licensed activity is conducted.

3. [See, also, subd. 3 above] The department shall cause to be expunged or otherwise destroyed, within five years from the date of receipt thereof, any record of the name of any patient received by it pursuant to the filing requirements of subdivision six of section thirty-three hundred thirty-one, subdivision four of section thirty-three hundred thirty-three, and subdivision four of section thirty-three hundred thirty-four of this article.

§ 3371. Confidentiality of certain records, reports, and information

1. No person, who has knowledge by virtue of his office of the identity of a particular patient or research subject, a manufacturing process, a trade secret or a formula shall disclose such knowledge, or any report or record thereof, except:

(a) to another person employed by the department for purposes of executing provisions of this article; or

(b) pursuant to judicial subpoena or court order in a criminal investigation or proceeding; or

(c) to an agency, department of government, or official board authorized to regulate, license or otherwise supervise a person who is authorized by this article to deal in controlled substances, or in the course of any investigation or proceeding by or before such agency, department or board.

(d) to a central registry established pursuant to this article.

2. In the course of any proceeding where such information is disclosed, except when necessary to effectuate the rights of a party to the proceeding, the court or presiding officer shall take such action as is necessary to insure that such information, or record or report of such information is not made public.

§ 3372. Practitioner patient reporting

It shall be the duty of every attending practitioner and every consulting practitioner to report promptly to the commissioner, or his duly designated agent, the name and, if possible, the address of, and such other data as may be required by the commissioner with respect to, any person under treatment if he finds that such person is an addict or a habitual user of any narcotic drug. Such report shall be kept confidential and may be utilized only for statistical, epidemiological or research purposes, except that those reports which originate in the course of a criminad proceeding other than under section 81.25 of the mental hygiene law shall be subect only to the confidentiality requirements of section thirty-three hundred seventy-one of this article.

§ 3373. Confidential communications

For the purposes of duties arising out of this article, no communication made to a practitioner shall be deemed confidential within the meaning of the civil practice law and rules relating to confidential communications between such practitioner and patient.

§ 3374. Notification by licensee

Persons licensed or certified pursuant to this article shall be under a continuing duty to promptly notify the department of:

1. Each incident or alleged incident of theft, loss or possible diversion of controlled substances manufactured, ordered, distributed or possessed by such person;

2. Any charge or proceeding brought in any court or before any governmental agency, state or federal, in which it is alleged that the licensee, its employees, subsidiaries, managing officers, or directors has failed to comply with the provisions of the federal controlled substances act or the laws of any state relating to controlled substances.

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TITLE VII—OFFENSES, VIOLATIONS AND ENFORCEMENT
(in part)

§ 3385. Enforcement

1. (a) The department and its representatives shall have access during business hours to all orders, prescriptions or records required to be kept under this article.

(b) Orders, prescriptions and records required to be kept under this article shall be maintained at the premises where the licensed activity is conducted.

2. For the purposes of this article, each employee of the department designated by the commissioner shall possess all of the powers of a peace officer.

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§ 3397. Fraud and deceit

1. No person shall:

(a) obtain or attempt to obtain a controlled substance, a prescription for a controlled substance or an official New York State prescription form,

(i) by fraud, deceit, misrepresentation or subterfuge; or

(ii) by the concealment of a material fact; or

(iii) by the use of a false name or the giving of a false address;

(b) wilfully make a false statement in any prescription, order, application, report or record required by this article;

(c) falsely assume the title of, or represent himself to be, a licensed manufacturer, distributor, pharmacy, pharmacist, practitioner, researcher, approved institutional dispenser, or other authorized person, for the purpose of obtaining a controlled substance;

(d) make or utter any false or forged prescription or false or forged written order;

(e) affix any false or forged label to a package or receptacle containing controlled substances; or

(f) imprint on or affix to any controlled substance a false or forged code number or symbol.

2. Possession of a false or forged prescription for a controlled substance by any person other than a pharmacist in the lawful pursuance of his profession shall be presumptive evidence of his intent to use the same for the purpose of illegally obtaining a controlled substance.

3. Any person who, in the course of treatment, is supplied with a controlled substance or a prescription therefore by one practitioner and who, without disclosing the fact, is supplied during such treatment with a controlled substance or a prescription therefor by another practitioner shall be guilty of a violation of this article.

Appendix E, Opinion, Application for Stay, October 28, 1975 (96 S. Ct. 164).

SUPREME COURT OF THE UNITED STATES

No. A-368

MR. JUSTICE MARSHALL, Circuit Justice.

This is an application for a stay of the judgment of a Three-judge court sitting in the Southern District of New York. The applicant, the Commissioner of Health of the State of New York, has been enjoined by the three-judge court from enforcing certain provisions of New York's Public Health Law (the Law). Respondents are various physicians, organizations of physicians, and patients in the State of New York who successfully brought suit to have those provisions declared unconstitutional.

The provisions at stake are those parts of §§ 3331 (6), 3332 (2)(a), and 3334 (4) of the Law that require the names and address of each patient receiving a Schedule II controlled substance to be reported to the applicant. Schedule II drugs are those that have a high potential for abuse, but also have an accepted medical use. They include opiates and amphetamines. Under the state law, a doctor prescribing a Schedule II drug does so on a special serially numbered triplicate prescription form. One copy is retained by the doctor, a second goes to the pharmacist (if applicable), and the last copy goes to the applicant, who transfers the data, including the name and address of the patient, from the prescription to a centralized computer file.

Respondents brought this action shortly after the effective date of the computerization program, alleging violations of their constitutional rights under 42 U. S. C. § 1983 and grounding jurisdiction on 28 U. S. C. § 1343 (3).

Specifically, respondents claimed that mandatory disclosure of the name of a patient receiving Schedule II drugs violated the patient's right of privacy and interfered with the doctor's right to prescribe treatment for his patient solely on the basis of medical considerations. A three-judge court was convened. *Roe* v. *Ingraham,* 480 F. 2d 102 (CA2 1973).

At trial, various respondents testified that they were inhibited from using or prescribing Schedule II drugs they otherwise found beneficial because of a reluctance to disclose their or their patients' identities to the State. While questioning respondents' standing to sue, the State asserted that knowledge of patients' names was necessary to enable the computer system to detect drug abuse. When put to its proof by respondents, however, the State eventually conceded that the names and addresses of patients were useful in detecting only one abuse: patients who go from doctor to doctor (using the same name on each visit) in order to obtain an excess supply of drugs. Thereupon respondents showed that in 15 months of operation the computer had located only one suspected "doctor-shopper" while processing over 125,000 prescriptions per month. Thus respondents contended that the centralization of patients' names and addresses served no compelling state interest sufficient to offset the asserted invasion of privacy.

The three-judge court accepted respondents' arguments. The court read our decisions in *Roe* v. *Wade,* 410 U. S. 113 (1973), and *Doe* v. *Bolton,* 410 U. S. 179 (1973), as placing the doctor-patient relationship among those zones of privacy accorded constitutional protection. While noting that *Roe* and *Doe* concerned the most intimate of personal relations, sexual intimacy and the decision to bear a child, the court refused to hold the doctor-patient relationship constitutionally protected only when matters of childbearing were at stake. Rather, it noted the intimate nature

of a patient's concern about his bodily ills and the medication he takes, and held that these matters too are protected by the constitutional right to privacy. While reaching this conclusion primarily on the basis of *Roe* and *Doe,* the court drew some support from the concurring and dissenting opinions in *California Bankers Assn.* v. *Shultz,* 416 U. S. 21, 78, 79, 91 93 (1974), which it read as indicating that a majority of this Court would accord constitutional protection, at least against a wholesale reporting requirement, to all "intimate areas of an individual's personal affairs." *Id.,* at 78 (POWELL, J., concurring). Upon finding that respondents had a protected privacy interest in the medication they received, the court balanced that interest against the State's need for patient names, and concluded that, with one suspect uncovered over 15 months, the need shown was ephemeral. "The diminution of a constitutionally guaranteed freedom is too great a price to pay for such a small governmental yield." *Roe* v. *Ingraham,* slip op., at 16 (footnote omitted).

Finding those portions of the Law that demanded disclosure of patients' names and addresses to the State to be unconstitutional on the facts, the court enjoined the State from enforcing those provisions and from accepting for filing prescriptions or other documents disclosing the identities of patients receiving Schedule II drugs. The court also ordered the destruction of any name-bearing prescription forms in the State's possession and the expungement of names from all computer records. The court stayed the destruction and expungement order pending disposition of the case by this Court; it refused, however, to stay its declaration of unconstitutionality and its injunction against enforcement of the provisions and acceptance of incoming prescriptions.

Thus the application for stay now before me concerns only those matters the District Court refused to stay. The principles that govern a Circuit Justice's in-chambers review of stay applications are well known. A single

Justice will grant a stay only in extraordinary circumstances. Certainly the judgment of the lower court, which has considered the mater at length and close at hand, and has found against the applicant both on the merits and on the need for a stay, is presumptively correct. To prevail here the applicant must meet a heavy burden of showing not only that the judgment of the lower court was erroneous on the merits, but also that the applicant will suffer irreparable injury if the judgment is not stayed pending his appeal.

MR. JUSTICE POWELL has succinctly stated the considerations pertinent to evaluating these two factors:

> "As a threshold consideration, Justices of this Court have consistently required that there be a reasonable probability that four members of the Court will consider the issue sufficiently meritorious to grant certiorari or to note probable jurisdiction. See *Mahan* v. *Howell,* 404 U. S. 1201, 1202; *Organized Village of Kake* v. *Egan,* 80 S. Ct. 33, 4 L. Ed. 2d 34 (1959). Of equal importance in cases presented on direct appeal—where we lack the discretionary power to refuse to decide the merits—is the related question whether five Justices are likely to conclude that the case was erronueously decided below. Justices have also weighed heavily the fact that the lower court refused to stay its order pending appeal, indicating that it was not sufficiently persuaded of the existence of potentially irreparable harm as a result of enforcement of its judgment in the interim." *Grames* v. *Barnes,* 405 U .S. 1201, 1203-1204 (1972) (POWELL, J., in chambers).

See also *Aberdeen & Rockfish R. Co.* v. *SCRAP,* 409 U. S. 1207, 1218 (1972) (BURGER, C. J., in chambers); *Railway Express Agency* v. *United States,* 82 S. Ct. 466, 7 L. Ed. 432 (1962) (Harlan, J., in chambers); *United Fuel Gas Co.* v. *Public Service Comm'n,* 278 U. S. 322, 326 (1929).

Applying these standards to the application before me, I conclude a stay should not be granted. The three-judge court gave careful consideration to applicant's motion for a stay and, indeed, granted one insofar as it deemed necessary to prevent irreparable harm to applicant's interests. Applicant has shown nothing to persuade me the lower court erred. If applicant's position is sustained on appeal, all the data it is precluded from processing by the District Court's order will be readily available from the State's doctors and pharmacists, who are required by law to retain the complete prescription form for five years. The information now denied the State's computers can thus be located and tabulated at a later date. While the State may suffer delay in the complete implementation of its computerization program, delay alone is not, on these facts, irreparable injury.

I conclude that applicant would suffer no irreparable injury if a stay is denied. This conclusion necessarily decides the application and renders unnecessary consideration of the possibility, since this case involves an appeal as of right, that applicant will be able to convince five Justices to reverse the three-judge court. I do note, however, that the right to privacy is a sensitive and developing area of the law and that the three-judge court did not apply it in a manner plainly inconsistent with our decisions. Likewise, the court's conclusion that respondents had standing seems in accord with the liberal standing decisions of this Court. Of course, this conclusion and my denial of a stay on the papers now before me is not to be taken as a reflection of my views on the merits of this case, or as an indication of the ultimate disposition of the case in this Court.

The application is denied.

APPENDIX

MAY 21 1976

Supreme Court of the United States

OCTOBER TERM, 1975

75-839

ROBERT P. WHALEN, as Commissioner of Health of the State of New York,

Appellant,

against

RICHARD ROE, an infant by ROBERT ROE, his parent; JOHN DOE, an infant by MARY DOE, his parent, JAMES MOE, an infant by MICHAEL MOE, his parent; JANE POE, MATTHEW T. BRODY, ISRAEL L. SCHMIERER AND EMPIRE STATE PHYSICIANS GUILD, INC.,

Appellees,

and

GEORGE PATIENT, MARTHA PATIENT, GERALD L. LUSTIG, and THE AMERICAN FEDERATION OF PHYSICIANS AND DENTISTS,

Intervenor-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

JURISDICTIONAL STATEMENT FILED DECEMBER 15, 1975

PROBABLE JURISDICTION NOTED FEBRPARY 23, 1976

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Relevant Docket Entries—District Court.

73 Civ. 1303 and 73 Civ. 1431

73 Civ. 1303 (Roe v. Ingraham)

DATE	PROCEEDINGS
3/29/73	Filed Complaint and issued Summons (73 Civ. 1303).
4/ 5/73	Filed Affidavit of A. Seth Greenwald; Assistant Attorney General, etc.
4/ 5/73	Filed Memorandum of Law in support of Plaintiff's Motion for a Three Judge Court.
4/ 5/73	Filed Memorandum of Law in opposition to convening a Three Judge Court and to dismiss the Complaint.
4/ 6/73	Filed Plaintiff's Order (ret. 4/6/73).
4/ 6/73	Filed Plaintiff's Order to Show Cause and Temporary Restraining Order (ret. 4/6/73).
4/ 6/73	Filed Plaintiff's ORDER. Ordered that: Plaintiff's motion for an order convening a three judge court pursuant to 28 U.S.C. Sec. 2281 and 2284 is denied; Plaintiff's motion for a preliminary and permanent injunction is denied; the complaint is dismissed for want of substantial federal question; and the temporary restraining order granted on 3/29/73 is dissolved. Execution stayed until 4/9/73 to permit plaintiff to seek a stay and to perfect a new appeal Carter, J. M/N.
4/10/73	Filed Opinion #39394 Motions for preliminary and permanent injunctions are denied and temporary restraining order is dissolved. Complaints are dismissed for want of substantial federal question. So Ordered. Carter, J. M/N.

Relevant Docket Entries—District Court.

DATE	PROCEEDINGS
4/ 9/73	Filed Notice of Appeal.
6/18/73	Filed Defendant's Notice of Motion to Dismiss (ret. 6/25/73).
6/21/73	Filed Memorandum of Law for Defendant to Dismiss Complaint with attached Second Interim Report.
6/25/73	Filed Plaintiff's reply memorandum in support of motion for a preliminary injunction and in opposition to Defendant's motion to Dismiss.
6/ 8/73	Filed Opinion and true copy of USCA mandate: Ordered that the District Court Order dismissing the complaint is reversed with instructions; costs taxed against appellee (no bill of costs attached) (Also in 73 Civ. 1431 RLC) (Entered 7/14/73) M/N.
8/27/73	Filed opinion #39786—heard before a Three Judge Panel—The defendant's motion to dismiss is denied. The motion for preliminary injunction is denied and the restraining order heretofore entered is vacated. So Ordered. Judges Feinberg (Cir. Judge), Wyatt and Carter. M/N
10/16/73	Filed defendants Answer to complaint (also 73-1431).
7/ 3/74	Filed Stipulation and Order that, for purposes of the above entitled action, the documents indicated herein constitute the legislative history of the sections in Article 33 of the New York Public Health Laws, etc. Carter, J.

Relevant Docket Entries—District Court.

DATE	PROCEEDINGS
11/21/74	Filed consent pretrial order—Carter, J.
11/22/74	Filed consent pretrial order (#2) Carter, J.
11/27/74	Filed Defendant's trial memorandum.
11/27/74	Filed order that the trial (Three Judge Court; Feinberg, (J. Wyatt, J. and Carter, J.) will be held on 12/2/74. Ordered that the parties shall submit trial memoranda by 11/27/74. Original to be filed with the Clerk of the Court, copies thereof delivered to each member of the Three Judge Court—Carter, J. M/N
11/27/74	Filed Plaintiffs' and Intervenors' Trial memorandum.
11/27/74	Filed order designating the following judges in addition to Judge Carter, to hear and determine cause: Wilfred Feinberg, C.J. and Inyer B. Wyatt, J.—Kaufman, Ch. J.—C.A.
12/ 2/74	Filed consent pretrial order that 73 Civ. 1431 shall be consolidated for trial and tried jointly with this proceeding—Carter, J.
12/ 3/74	Filed Plaintiffs' memorandum of law in support for a preliminary injunction.
12/ 3/74	Filed reply memorandum in support of plaintiffs' motion for a preliminary injunction and in opposition to defendant's motion to dismiss the complaint.
1/29/75	Filed Plaintiffs' memorandum in support of motion for a Three Judge Court and T.R.O.

Relevant Docket Entries—District Court.

DATE	PROCEEDINGS
1/29/75	Filed Defendant's memorandum of law in opposition to motion to convene a Three Judge Court and to dismiss.
2/28/75	Filed Transcript of Record of Proceedings dated December 2, 1974—(also in 73 Civ. 1431).
3/28/75	Filed Defendant's post trial memorandum (also for 73-1431).
3/28/75	Filed Plaintiffs' post trial brief with proposed Findings of Fact and Conclusions of Law (also for 73-1431).
3/28/75	Filed Intervenors' post trial memorandum of law.
4/ 1/75	Filed Plaintiffs' reply post trial brief.
4/11/75	Filed Defendant's affidavit and notice of motion to amend pre-trial order as indicated and for judgment in favor of defendant on the close of plaintiffs' prima facie case, etc. (returnable 4/25/75).
4/11/75	Filed deposition of Joseph A. Bonacci on 12/6/74 M/N.
4/11/75	Filed deposition of State of New York by Joseph L. Cannizzaro on 12/5/74 M/N.
4/22/75	Filed Plaintiffs' affidavit in opposition to certain portions of defendant's motion to amend.
4/22/75	Filed deposition of Dr. Jerry Martin Rosenberg taken on 12/4/74.
4/22/75	Filed deposition of Joseph Jules Wasserman, a witness taken on 12/4/74.

Relevant Docket Entries—District Court.

DATE	PROCEEDINGS
4/22/75	Filed transcript of record of proceedings dated 12/2/74 (copy and not certified).
7/28/75	Filed memo endorsed on defendant's motion to amend pre-trial: Defendant's motion to amend pretrial order to include exhibit A-N inclusive is granted. Defendant's motion to exclude the testimony of Joseph Wasserman and to grant judgment to defendant at the close of plaintiffs' prima facie case is denied. So Ordered—Carter, J. (for 73-1303 and 73-1431).
8/13/75	Filed Opinion #42959 Three Judge Court holding that so much of sections 3331(b), 3332(2) and 3334(4) of the New York Public Health Law as requires reporting to a state authorities. The names and addresses of patients who receive Schedule II drugs and medication is an unconstitutional interference with plaintiffs' rights of privacy guaranteed under the 16th Amendment. The decision makes unnecessary an evaluation of the state measures to insure confidentiality. Settle order and notice. Judges Feinberg, Wyatt and Carter. M/N.
9/17/75	Filed Plaintiffs' affidavit of Michael Lesch in support of Plaintiffs proposed judgment.
10/ 3/75	Filed affidavit and order substituting Robert P. Whalen Commissioner of Health of the State of New York as defendant in place of his predecessor, Hollis S. Ingraham. Carter, J.

Relevant Docket Entries—District Court.

DATE	PROCEEDINGS
10/ 9/75	Filed Final Order and Judgment that sections 3331(6), 332(2)(a) and 333(4) of the New York Public Health Law, insofar as they require disclosure to the State of New York the identity of patients receiving prescriptions for Schedule II controlled substances are declared unconstitutional, etc. Defendant's are enjoined from enforcing said provisions. Paragraphs 3 and 4 of this judgment are stayed on condition that defendant timely file a notice of appeal to the U.S. Supreme Court. Feinberg, C. J., Wyatt, J. & Carter, J. Judgment entered—Clerk M/N.
10/20/75	Filed Defendant's notice of appeal to the U.S. Supreme Court.
10/21/75	Filed order (with letter attached) that Defendant's letter of 10/16/75 is treated as a motion for further stay of the order of 10/9/75. Motion for a further stay is denied —Feinberg, C.J., Wyatt, J. and Carter, J. M/N.
11/ 5/75	Filed letter by Supreme Court of the U.S. Office of the Clerk, dated 10/30/75, forwarding copy of opinion by Justice Marshall dated 10/28/75.
11/ 5/75	Filed copy of Justice Marshall's memorandum opinion of 10/28/75, denying the application for a stay in this action.

Relevant Docket Entries—District Court.

73 Civ. 1431 (Patient v. Ingraham)

DATE	PROCEEDINGS
4/ 4/73	Filed complaint and issued summons (73 Civ. 1431).
4/12/73	Filed Plaintiffs' notice of appeal.
4/19/73	Filed transcrpit of record proceedings dated April 6, 1973.
4/19/73	Filed Notice to Docket Clerk that record on appeal has been certified and transmitted to USCA on 4/19/73.
6/ 8/73	Filed opinion and true copy of USCA mandate—same as 73-1303; reversing order of the District Court and ordering a Three Judge Court.
10/16/73	Filed Defendant's answer to complaint.
11/27/74	Filed order—same as 73-1303; setting trial date and date for submitting memoranda.
11/27/74	Filed order—same as 73-1303, designating members of Three Judge Court.
12/ 2/74	Filed consent pretrial order—same as 73-1303, ordering consolidation with 73-1303, Carter, J.
2/28/75	Filed transcript of record of proceedings dated 12/2/74.
3/28/75	Filed Defendant's post trial brief (73-1303).
3/28/75	Filed Plaintiffs' post trial brief (73-1303).
4/ 1/75	Filed Plaintiffs' post trial memorandum of law.

Relevant Docket Entries—District Court.

DATE	PROCEEDINGS
8/13/75	Filed Opinion #42959—same as in 73-1303 holding the challenged sections of the N Y Public Health Law, to be unconstitutional as a violation of the Right to Privacy.
9/17/75	Filed affidavit of Michael Lesch in support of plaintiff's proposed judgment. (73-1303)
10/ 8/75	Filed Final Order and Judgment—same as 73-1303.
10/21/75	Filed order that Defendant's motion for a stay is denied. (73-1303)

Complaint (Roe, 73 Civ. 1303).

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

RICHARD ROE, an infant, by Robert Roe, his parent, JOHN DOE, an infant, by Mary Doe, his parent, JAMES MOE, by Michael Moe his parent, JANE POE, MATTHEW T. BRODY, ISRAEL L. SCHMIERER and EMPIRE STATE PHYSICIANS GUILD, INC.,

Plaintiffs,

against

HOLLIS S. INGRAHAM, as Commissioner of Health of the State of New York,

Defendant.

Plaintiffs, by their attorneys Shea Gould Climenko & Kramer and Solomon Z. Ferziger, for their complaint herein, allege as follows:

1. This is a civil action brought by the plaintiffs, on their own behalf and on behalf of all others similarly situated, for a temporary and permanent injunction against enforcement of those provisions of Article 33 of the New York Public Health Law (referred to hereinafter as the "Act") which require physicians to record, on prescriptiton forms to be filed with the State of New York, the identity of patients using medications set forth in Schedule II of Section 3306 of the Act (referred to hereinafter as "Schedule II controlled substances") and to declare such requirement violative of the Fourteenth Amendment of the United States Constitution.

2. Jurisdiction is conferred upon this Court pursuant to 28 U.S.C. Sections 1343(3), 2281, 2201 and 2202.

3. Each of the individual plaintiffs is a citizen of the United States, a resident of New York State and at least one resides in the Southern District of New York.

4. Plaintiffs Richard Roe, Joe Doe and James Moe (who are infants appearing by their parents) and Jane Poe are patients regularly receiving prescriptions for medications listed on Schedule II of Section 3306 of Article 33 of the New York Public Health Law. The aforesaid plaintiffs are suing under fictitious names to avoid public disclosure of their identity.

5. Plaintiffs Matthew T. Brody and Israel L. Schmierer are physicians who, in the course of their practices, prescribe for recognized medical purposes, drugs listed on Schedule II of Section 3306 of Article 33 of the New York Public Health Law.

6. Plaintiff Empire State Physicians Guild, Inc. is a Membership Corporation organized and existing under the laws of the State of New York.

7. Defendant Hollis S. Ingraham is Commissioner of Health of the State of New York and is sued herein in that capacity.

8. On June 8, 1972, Governor Nelson A. Rockefeller signed into law, Laws of New York 1972, Chapter 878, entitled "An Act to amend the public health law and the penal law, in relation to controlled substances and dangerous drugs, and repealing articles thirty-three, thirty-three-A and thirty-three-B of the Public Health Law, and section 220.00 of the penal law in relation thereto." (The text of the Act is set forth herein as Appendix A.) By its terms the Act becomes effective on April 1, 1973.

9. The Act on its face and as construed and applied by defendant requires (1) that, except as expressly authorized by a provision for emergency oral prescriptions, all Schedule II controlled substances may be prescribed or dispensed only upon an official New York State prescription (Section 3338(2)); (2) that such prescription shall be prepared in triplicate and the original and both copies shall contain, *inter alia*, the name, address and age of the ultimate user for whom the substance is intended (Section 3332(2)); (3) that if a physician dispenses the substance, he shall keep the original prescription and forward two copies to the Department of Health (Section 3331(6)) and if a physician prescribes the substance, he shall retain one copy of the prescription, transmit the original and one copy of the pharmacist who retains the original and files the copy with the Department of Health (Section 3333(4)); and (4) that the Department of Health may make disclosure of the information contained on such prescriptions to, *inter alia*, any "person who by virtue of his office is entitled to obtain such information" (Section 3371(1)(a)).

10. In or about January 1973, the Commissioner of Health promulgated certain rules and regulations with respect to controlled substances pursuant to authority therefore in the Act.

11. The Act on its face, and as construed and applied, violates the Fourteenth Amendment of the United States Constitution in that, by requiring disclosure of the identity of certain patients it invades the patient's right of privacy and confidentiality, infringes on the doctor's right to prescribe treatments for his patients solely on the basis of medical considerations and discriminates against persons suffering from certain diseases by requiring their identification to a governmental agency as a condition to receiving medical treatment for their illnesses.

12. This suit involves a genuine case of controversy between plaintiffs and defendant.

13. The plaintiffs have no plain, speedy or adequate remedy at law and will suffer irreparable injury unless a preliminary and permanent injunction is granted.

WHEREFORE, plaintiffs pray that the following relief be granted:

1. That a three-judge court be convened as provided in 28 U.S.C. Sections 2281 and 2284 to declare unconstitutional and enjoin the enforcement of Sections 3331(6), 3332(2) (a) and 3333(4) of the Act insofar as they require disclosure to the State of the identity of patients using Schedule II controlled substances.

2. That the defendant, his agents, servants and employees

(a) be enjoined from distributing New York State prescription forms requesting the identity of patients receiving prescriptions for Schedule II controlled substances;

(b) be enjoined from accepting for filing New York State prescription forms containing the identity of patients receiving prescriptions for Schedule II controlled substances;

(c) be enjoined from requiring physicians or pharmacists to complete and file prescription forms containing the identity of patients receiving prescriptions for Schedule II controlled substances; and

(d) be ordered to destroy any New York State prescription forms previously filed containing the identity of patients receiving prescriptions for Schedule II

controlled substances and any records made therefrom.

3. That an injunction, *pendente lite*, be granted to the plaintiffs against the defendant, his agents, servants and employees for the relief sought in paragraphs 2(a), (b) and (c) hereinabove and ordering that defendant, his agents, servants and employees deposit in the registry of this Court any New York State prescription forms previously filed containing the identity of patients receiving prescriptions for Schedule II controlled substances and any records made from such forms.

4. That the plaintiffs be granted such other and further relief as the Court may deem just and proper.

Dated: New York, New York, March 28, 1973.

SHEA GOULD CLIMENKO & KRAMER

By MICHAEL LESCH
A Member of the Firm

and

SOLOMON Z. FERZIGER, Esq.

Attorneys for Plaintiffs.

Complaint (Patient, 73 Civ. 1431).

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

GEORGE PATIENT, MARTHA PATIENT, GERALD L. LUSTIG and THE AMERICAN FEDERATION OF PHYSICIANS AND DENTISTS,

Plaintiffs,

—against—

HOLLIS S. INGRAHAM, as Commisioner of Health of the State of New York,

Defendant.

Plaintiffs, by their attorneys, Norwick, Raggio & Jaffe, as cooperating attorneys for the New York Civil Liberties Union, for their complaint, allege as follows:

1. This is a civil suit by the plaintiffs, on their own behalf and on behalf of others similarly situated, for a temporary and permanent injunction against enforcement of those provisions of Article 33 of the New York Public Health Law (referred to hereinafter as the "Act") which require physicians to record, on prescription forms to be filed with the State of New York, the identity of patients using medications set forth in Schedule II of Section 3306 of the Act (referred to hereinafter as "Schedule II controlled substances") and to declare such requirement violative of the Fourteenth Amendment of the United States Constitution.

2. Jurisdiction is conferred upon this court pursuant to 28 U.S.C. 1331, 1343(3), 2281, 2201 and 2202 as well as

by 42 U.S.C. 1983 and by the Commerce Clause of the United States Constitution, Article 1, Section 8 and by the Fourteenth Amendment of the United States Constitution.

3. The amount in controversy in this action is in excess of $10,000.

4. Each of the individual plaintiffs is a citizen of the United States, a resident of New York State and at least one resides in the Southern District of New York.

5. Plaintiff George Patient is a patient regularly receiving prescriptions for medication listed on Schedule II, namely, Hycodan and Percodan, in treatment for his conditions resulting from his status as a post-operative cancer patient. Plaintiff Martha Patient is a patient regularly receiving prescriptions for medication listed on Schedule II, namely Demerol, in treatment of a migraine condition. These plaintiffs are suing under fictitious names to avoid public disclosure of their identity.

6. Plaintiff Lustig is a physician who in the course of his practice prescribes for recognized medical purposes drugs listed on Schedule II and who has prescribed Schedule II drugs for plaintiff George Patient.

7. Plaintiff American Federation of Physicians and Dentists is an unincorporated association of physicians and dentists.

8. Defendant Hollis S. Ingraham is Commissioner of Health of the State of New York and is sued herein in that capacity.

9. On June 8, 1972, Governor Nelson A. Rockefeller signed into law, Laws of New York 1972, Chapter 878, en-

titled "An Act to amend the public health law and the penal law, in relation to controlled substances and dangerous drugs, and repealing articles thirty-three, thirty-three-A and thirty-three-B of the Public Health Law, and section 220.00 of the penal law in relation thereto." (The text of the Act is set forth herein as Appendix A.) By its terms the Act becomes effective on April 1, 1973.

10. The Act on its face and as construed and applied by defendant requires (1) that, except as expressly authorized by a provision for emergency oral prescriptions, all Schedule II controlled substances may be prescribed or dispensed only upon an official New York State prescription (Section 3338(2)); (2) that such prescription shall be prepared in triplicate and the original and both copies shall contain, *inter alia,* the name, address and age of the ultimate user for whom the substance is intended (Section 3332(2)); (3) that if a physician dispenses the substance, he shall keep the original prescription and forward two copies to the Department of Health (Section 3331(6)) and if a physician prescribes the substance, he shall retain one copy of the prescription, transmit the original and one copy to the pharmacist who retains the original and files the copy with the Department of Health (Section 3333(4)); and (4) that the Department of Health may make disclosure of the information contained on such prescriptions to, *inter alia,* any "person who by virtue of his office is entitled to obtain such information" (Section 3371(1)(a)).

11. In or about January 1973, the Commissioner of Health promulgated certain rules and regulations with respect to controlled substances pursuant to authority therefor in the Act.

12. The Act on its face, and as construed and applied, violates the Fourteenth Amendment of the United States

Constitution in that, by requiring disclosure of the identity of certain patients it invades the patient's right of privacy and confidentiality, infringes on the doctor's right to prescribe treatments for his patients solely on the basis of medical considerations and discriminates against persons suffering from certain diseases by requiring their identification to a governmental agency as a condition to receiving medical treatment for their illnesses.

13. The Act on its face conflicts with, is inconsistent with and overlaps federal law and federal regulation and is thus void, being in conflict with the commerce power of the United States government and the laws and regulations enacted by the United States pursuant thereto.

WHEREFORE, plaintiffs pray that the following relief be granted:

1. That a three-judge court be convened as provided in 28 U.S.C. 2281 and 2284 to declare unconstitutional and enjoin the enforcement of Section 3331(6), 3332(2)(a) and 3333(4) of the Act in so far as they require disclosure to the State of the identity of patients using Schedule II controlled substances.

2. That the defendant, his agents, servants and employees

(a) be enjoined from distributing New York State prescription forms requesting the identity of patients receiving prescriptions for Schedule II controlled substances;

(b) be enjoined from accepting for filing New York State prescription forms containing the identity of patients receiving prescriptions for Schedule II controlled substances;

(c) be enjoined from requiring physicians or pharmacists to complete and file prescriptiton forms containing the identity of patients receiving prescriptions for Schedule II controlled substances; and

(d) be ordered to destroy any New York State prescription forms previously filed containing the identity of patients receiving prescriptions for Schedule II controlled substances and any records made therefrom.

3. That an injunction, *pendente lite,* be granted to the plaintiffs against the defendant, his agents, servants and employees for the relief sought in paragraphs 2(a), (b) and (c) hereinabove and ordering that defendant, his agents, servants and employees deposit in the registry of this Court any New York State prescription forms previously filed containing the identity of patients receiving prescriptions for Schedule II controlled substances and any records made from such forms.

4. That the plaintiffs be granted such other and further relief as the Court may deem just and proper.

Dated: New York, New York, April , 1973.

NORWICK, RAGGIO & JAFFE

By .....
A Member of the Firm

Affidavit of A. Seth Greenwald.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

RICHARD ROE, an infant by ROBERT ROE, his parent, JOHN DOE, an infant by MARY DOE, his parent, JAMES MOE, an infant by MICHAEL MOE, his parent, JANE POE, MATTHEW T. BRODY, ISRAEL L. SCHMIERER, and EMPIRE STATE PHYSICIANS GUILD, INC.,

Plaintiffs,

against

HOLLIS S. INGRAHAM, as Commissioner of Health of the State of New York,

Defendant.

STATE OF NEW YORK }
COUNTY OF NEW YORK } ss.:

A. SETH GREENWALD, being duly sworn, deposes and says:

I am an Assistant Attorney General in the Office of Louis J. Lefkowitz, Attorney General of the State of New York, attorney for defendant and make this affidavit to present several pertinent procedural considerations to the court.

I.

The institution of the law suit with fictitious names raises the question considered in *Roe* v. *State of New York,* 49 F.R.D. 279, 8 A.L.R. Fed. 670 (S.D.N.Y. 1970). Since the "Roes", "Does" and "Moes" are the real parties in interest the Court and the defendant should be given the names of same to insure the existence of actual contro-

versy. This can be accomplished by the filing of an affidavit containing the true name and identity of the fictitious plaintiffs. This was done in *Doe* v. *Lavine,* 72 Civ. 2517 (S.D.N.Y.). After this is done, your deponent has no objection to taking whatever steps necessary to insure continued anonymity.

It should be pointed out that Dr. Schmierer may well have named several of the infant plaintiffs in his affidavit. Mentioned therein are Howard Goldstein and James Maiorana.

II.

On March 29, 1973, this Court issued a general temporary restraining order against defendant. However this is not a class action and plaintiffs make none of the required recitals in their complaint, except that it is on "behalf of all others similarly situated" (par. "1"). In all other respects it fails to comply with Rule 23, F.R.C.P. In particular we wonder whether the representative parties adequately represent the class. 23(a)(4). The partys' attorney must be qualified, experienced and generally able to conduct the proposed litigation. *Eisen* v. *Carlisle & Jacquelin,* 391 F. 2d 555, 562 (2d Cir. 1968). We do not contend plaintiffs' attorneys are not but, on the other hand, they have not so affirmatively stated.

In view of the lack of a class action, Rule 23, the t.r.o. should immediately be limited to plaintiffs' prescriptions and no others. Also no pharmacists are represented so that the plaintiffs should not purport to seek relief on their behalf.

In sum, this action should not be treated as a class action unless there is compliance with Rule 23.

III.

In view of the confusion engendered by the original t.r.o. with the subsequent modification, we urge that this action, if it is to be dismissed, be done with expedition. If, as we contend, the public health is endangered by the continuation of any restraints on the law, this Court should not extend the t.r.o. and quickly decide the case. We believe that at this time the plaintiffs have not shown any harm by letting the law go into complete operation. They only express conjectures and vague fears in the distant future. If they are, by chance, successful, full relief can be rendered at that time. However at this time there is no need for relief since it is not the recording of data that is a possible invasion of privacy but the ultimate revelation of same. Of course, we contend this will not occur and if the plaintiffs took the effort to fully investigate defendant's proposed procedures they would have been aware of this. Rather they have acted out of fear, unsupported by facts.

WHEREFORE, your deponent respectfully requests that plaintiffs' motion be denied, the temporary restraining order dissolved, and the complaint dismissed with all possible dispatch.

(Sworn to by A. Seth Greenwald, April 4, 1973.)

Affidavit of Robert Whalen, M.D.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

RICHARD ROE, et al.,

Plaintiffs,

v.

HOLLIS S. INGRAHAM, M.D.,

Defendant.

STATE OF NEW YORK
COUNTY OF NEW YORK } ss.:

ROBERT WHALEN, M.D. being duly sworn deposes and says:

Deponent is the Second Deputy Commissioner of the New York State Department of Health and in such capacity has the direct responsibility under the Commissioner of Health for Department policy relating to controlled substances.

Chapter 878 of the Laws of 1972 enacting a new Article 33 to the Public Health Law was signed by Governor Rockefeller June 8, 1972.

The legislation was the result of extensive investigation by the Temporary Commission to Evaluate the Drug Laws into pertinent medical practice, extent of abuse, and avenue of diversion of legal drugs. Hearings were conducted throughout the State and the opinions of hundreds of experts were solicited.

The Department has proceeded to implement the provisions of the law including the requirement of a triplicate prescription. The procedural steps are as follows:

Upon the application by a practitioner, official New York State prescription forms are issued in groups of one hun-

dred serially numbered forms. For prescribing or dispensing a Schedule II substance, the practitioner will use the triplicate form. If he dispenses the substance, he will keep the original and forward two copies to the Department. If he prescribes the substance, he will give the patient the original and one copy. The patient will take both the original and the copy to the pharmacy. The pharmacist filling the prescription will sign his name upon the original and the copy and will note the date of delivery, and the registration number of the pharmacy. He will then, by the fifteenth of the following month, send the endorsed copy to the Department. He will retain the original for five years.

Once the Department has received the copies, it will be able to compile data which will uncover irregularities such as forgeries, fraudulent obtaining of Schedule II substances, and thefts of prescription blanks and their misuse by unauthorized persons. The information received by the Department will show if a patient has obtained prescriptions by going from doctor to doctor, or if stolen prescriptions are being used. This procedure will also indicate where there is a possibility of over-prescribing or over-dispensing of Schedule II drugs.

Drug abusers operate in part through legitimate medical channels. Prescriptions are raised and refilled repeatedly and ficititious patient names are used. Individual patients go to more than one physician for drug prescriptions to be used for nonmedical needs and there are instances of over-prescribing.

At the time this proceeding was commenced over 23,000 practitioners had submitted orders and been mailed triplicate prescription forms. Such forms have been ordered by and mailed to approximately 300 institutions in New York State.

The requirement for a triplicate prescription is one part of the broad control mechanism of narcotics, depressants, stimulants and hallucinogens provided for in Article 33.

The need for control has long been recognized and policies relating to socially condemned drugs date back at least to the Federal Harrison Anti-Narcotic Act of 1914, which required that doctors be registered under the Act and made the manner of securing drugs a matter of record. The original goal was to make the entire process of distribution in America a matter of record. A series of Federal acts continued such controls, the most recent of which is the Federal Controlled Substances Act of 1970. A similar pattern prevailed in the states with a Uniform Narcotics Act enacted in most of the states. Controls in New York State go back to about World War I and a basic Uniform Narcotic Drug Act was enacted in New York State in 1933.

THAT the Uniform Narcotic Drug Act, as enacted in New York State in 1933, requires that the full name and address of the patient be on the prescription. This requirement has existed until the present time in both the Public Health Law (Public Health Law § 3301 (32) and in the Federal Regulations (21 CFR § 306.05). The identity of the patient on the label has also been a requirement of both the State and Federal Laws.

THAT there is a need for control has been thoroughly documented. To review the statements and acts of President Nixon and Governor Rockefeller would be to repeat generally known information as to abuses and efforts made to curb such abuses. It would be difficult to envision a system of controls that would be effective which did not require a physician to identify the patient for whom a drug is prescribed.

Information as to the identity of patients has always been required and has been available as limited by the statute. Records required by the control provisions existing prior to April 1, 1973 are confidential and are only open to inspection by "federal, state, county and municipal officers,

whose duty it is to enforce the laws of the state or of the United States relating to narcotic drugs". The law effective April 1, 1973 does not make available information that was not available prior to April 1 and, as a matter of fact, places a greater cloak of confidentiality over this information. Public Health Law § 3371 prohibits disclosure by Department personnel except (1) pursuant to judicial subpoena or court order, (2) to agencies licensing persons authorized to deal in controlled substances and (3) to another person who by virtue of his office is entiled to obtain such information. This last exception is to allow disclosure internally within the Department to those with a controlled substance responsibility. The Temporary Commission to Evaluate the Drug Law stated in its interim report that "this would relate primarily to intra-departmental communications". The section further provides that where such information is disclosed in a proceeding the court shall insure that such information is not made public.

The Department is experienced in dealing with confidential data and gathers information, reports and statistics in such diverse areas as venereal disease, tuberculosis, cancer and medical rehabilitation and is the custodian of birth, death, fetal death, marriage and dissolution of marriage records. All Department staff and persons with duties requiring access to Department records are instructed to treat as confidential any information or data received or developed in the performance of their duties. Utmost care will be taken with respect to triplicate prescriptions to insure that only Department personnel with specific Controlled Substances functions have access to the information.

The pharmacists are provided with preaddressed envelopes to mail to the Department the copies of the prescriptions. The copies received by the Department, as well as the tapes or punch cards produced from them will be given special handling and kept in locked, secured areas

while not in use, with access thereto strictly circumscribed by the Commissioner. There will be no massive print out of patient names but, on the contrary, the availability of such information will be severely limited. Attached are detailed statements of Department procedures and policies on both security and confidential information.

Deponent has read the papers in this proceeding and it would appear that in many instances affiants are reading or interpreting the statute incorrectly.

The identity of the patient is required in the case of addicts and habitual users. The practitioner is not required to file the original and a copy of the individual official prescription required by Public Health Law § 3331 (6) for the treatment of addiction maintenance because § 3355 of the Public Health Law has specific reporting requirements for maintenance programs including the identity of the patient and the amount of drugs administered or dispensed. There is no discrimination between addicts and habitual users on the one hand and others for whom drugs may be prescribed.

The purpose of collecting copies of the prescriptions centrally is to increase the efficiency of the controls mandated by Article 33. The filing of the prescription does not indicate the medical condition for which the drug was prescribed, is not a recording of illness, does not impair the patient-doctor relationship and certainly does not result in ridicule, abuse or blackmail.

The affidavits of the physician in support of the injunction support a medical use for the drugs prescribed. That Schedule II drugs have a medical use is not in question. The schedules as set forth in the Public Health Law range from Schedule I, having no currently accepted medical use and a high potential for abuse to Schedule V which has a currently accepted medical use and a low potential for abuse. Schedule II drugs have a currently accepted medical use with severe restrictions and a high potential for abuse requiring strict controls.

A similar multiple prescription procedure has been in effect in California since 1940, in Illinois since 1958 and in Idaho since 1967. Experience indicates that computer accessibility of such information uncovers such irregularities as forgeries, fraudulent obtaining of narcotic drugs, theft of prescription blanks and their misuse by unauthorized persons and other abuses. To the best of deponent's knowledge no litigation in those states has questioned the disclosure of the identity of the person for whom the prescription is written.

The availability of such information to another person who by virtue of his office is entitled to obtain such information, as provided for in Public Health Law § 3371, heavily relied on by petitioners, is only to allow disclosure internally within the Department as set forth earlier in this affidavit.

It is unlawful for any person to administer or dispense a controlled substance except as expressly allowed by Article 33 of the Public Health Law. Specifically provided for to enable Schedule II controlled substances to be administered or dispensed is the official triplicate prescription. The elimination of such provision would prevent such substances from being administered or dispensed in the State of New York, there being no statutory alternative, and would create a vacuum.

The temporary restraining order has created confusion among practitioners and pharmacists. Many are under the mistaken belief that they need not comply with the triplicate prescription requirements of Article 33. Professional confusion is to the detriment of the health care needs of the citizens of New York State.

This affidavit is made in opposition to the request of the plaintiffs for a preliminary injunction and in opposition to the continuance of the temporary restraining order.

(Sworn to by Robert P. Whalen, M.D., April 3, 1973.)

Sample Prescription.

(See opposite ☞)

DISPENSER: RETAIN ONE COPY. SEND OTHER TO NEW YORK STATE HEALTH DEPARTMENT, BUREAU OF NARCOTIC CONTROL, 845 CENTRAL AVE., ALBANY, N. Y., 12206 BY 15TH OF NEXT MONTH. THIS RX MUST BE FILLED IN 30 DAYS

NOTE: Prescription must show quantity to be taken per dose, number of doses daily, and total quantity prescribed.

THIS SECTION TO BE COMPLETED BY DISPENSER

PHARMACY Rx NUMBER | DATE Rx FILLED MO DAY YR.

SCHEDULE II SUBSTANCE NDC NO.

PHARMACY BNDD NUMBER

DISPENSER SIGNATURE

A 0900203

FOR SINGLE PRESCRIPTION ONLY
PLEASE PRINT

Rx

MAXIMUM DAILY DOSAGE

PRACTITIONER SIGNATURE

New York State Prescription MC-77 (8/73)

PRACTITIONER NAME AND ADDRESS

TEL NO.

PRACTITIONER BNDD NUMBER

Rx DATE MO. DAY YR.

PATIENT LAST NAME | FIRST | AGE

PATIENT ADDRESS

ZIP

NEW YORK STATE HEALTH DEPARTMENT - Official New York State Prescription

Sample Prescription

BEST COPY AVAILABLE

Order Denying Plaintiffs' Motions, etc.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

73 Civ. 1303 (RLC)

RICHARD ROE, an infant by ROBERT ROE, his parent, JOHN DOE, an infant by MARY DOE, his parent, JAMES MOE, an infant by MICHAEL MOE, his parent, JANE POE, MATTHEW T. BRODY, ISRAEL L. SCHMIERER and EMPIRE STATE PHYSICIANS GUILD, INC.,

Plaintiffs,

—against—

HOLLIS S. INGRAHAM, as Commissioner of Health of the State of New York,

Defendant.

ORDER

Plaintiffs having applied for an order convening a three judrge court, pursuant to 28 U.S.C. §§ 2281 and 2284, on the ground that plaintiffs seek an interlocutory and permanent injunction restraining the enforcement, operation and execution of a state statute by restraining the action of an officer of such state upon the ground of the unconstitutionality of such statute and for an order enjoining defendant, his agents, servants and employees from enforcing those provisions of Article 33 of the New York Public Health Law, and this Court having previously granted an order restraining enforcement of certain provisions of Article 33 of the New York Public Health Law pending determination of plaintiffs' application for an order convening a three judge court and for a permanent injunction;

Order Denying Plaintiffs' Motions, etc.

AND defendant having opposed said motion, it is hereby

ORDERED that plaintiffs' motion for an order convening a three judge court pursuant to 28 U.S.C. §§ 2281 and 2284 be, and it hereby is, denied; and it is further

ORDERED that plaintiffs' motion for preliminary and permanent injunction is denied and complaints dismissed for want of a substantial federal question.

ORDERED that the temporary restraining order granted herein on March 29, 1973 be and is hereby dissolved. Execution stayed until 12 noon on Monday, April 9, 1973 to permit plaintiff to seek a stay and to perfect their appeal to the United States Court of Appeals.

Dated: New York, New York
April 6, 1973

s/ ROBERT L. CARTER
U.S.D.J.

Opinion Denying Plaintiff's Motion for an Order Convening a Three-Judge Court, etc.

Richard Roe, an infant by Robert Roe, his parent, et al., Plaintiffs,
and
George Patient et al., Intervenors,

v.

Hollis S. Ingraham, as Commissioner of Health of the State of New York, Defendant.

No. 73 Civ. 1303.

United States District Court, S. D. New York.

April 10, 1973.

Robert L. Carter, District Judge:

Opinion

The plaintiffs have made a narrow attack upon the comprehensive New York Controlled Substances Act, N.Y. Public Health Law § 3300 et seq. (McKinney's Consol. Laws, c. 45 Supp.1972), which attempts to regulate virtually all facets of the use and distribution of drugs in this state for which a prescription is required. The plaintiffs object only to those sections, specifically §§ 3331(6),[1] 3332(1), (2)(a),[2]

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[1] "§ 3331 Scheduled substances administering and dispensing by practioners.

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6. A practitioner dispensing a substance which may be prescribed only upon an official New York state prescription must at the time of such dispensing prepare an official New York prescription in the manner set forth in subdivision two of section

(*footnte continued on following page*)

Opinion Denying Plaintiff's Motion for an Order Convening a Three-Judge Court, etc.

(4),[3] 3338(2),[4] which, in combination, require physicians and pharmacists to file with the state copies of prescriptions for certain drugs which are described in detail in the

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(*footnote continued from preceding page*)

thirty-three hundred thirty-two of this article. The practitioner shall retain the original for a period of five years and shall file the two copies with the department by not later than the fifteenth day of the next month following the month in which the substance was delivered. . . ."

[2] "§ 3332 Making of official New York state prescriptions for scheduled substances.

1. No substance for which an official New York state prescription is required may be prescribed by a practitioner except on an official New York state prescription, and in good faith and in the course of his professional practice only.

2. Such prescription shall be prepared in triplicate, written with ink, indelible pencil or, apart from the practitioner's signature, typewriter. The original and both copies must contain the following:

(a) the name, address, and age of the ultimate user for whom the substance is intended. . . ."

[3] "§ 3333 Dispensing upon official New York state prescription.

1. A licensed pharmacist may, in good faith, and in the course of his professional practice, sell and dispense to an ultimate user controlled substances for which an official New York state prescription is required only upon the delivery to such pharmacist, within thirty days of the date such prescription was signed by an authorized practioner, of the original and one copy of such official New York state prescription.

• • • • •

4. The endorsed original prescription shall be retained by the proprietor of the pharmacy for a period of five years. The endorsed copy of such prescription shall be filed with the department by not later than the fifteenth day of the next month following the month in which the substance was delivered."

[4] "§ 3338 official New York state prescription forms.

• • • • •

2. Except as expressly authorized by section thirty-three hundred thirty-four, substances listed in schedule II may be prescribed or dispensed only upon an official New York state prescription. . . ."

statute under the heading of "Schedule II" drugs, § 3306. Concededly, although the statute does not require it, the state will enter the information it receives, including the name of the patient for whom the drug is prescribed, into a computer file. It is this mechanized collation of data, pursuant to which the state will have on file the names and addresses of patients who are users of prescribed drugs, that constitutes the gravaman of plaintiffs' complaint.

On March 29, 1973 the plaintiffs[5] petitioned this court for an order to show cause on a motion to convene a three judge court pursuant to 28 U.S.C. §§ 2281, 2284 on the ground that plaintiffs sought preliminary and permanent injunctions restraining the implementation of certain sections of the New York Controlled Substances Act (which was to become effective on April 1, 1973), which were allegedly constitutionally infirm. The plaintiffs further sought a temporary restraining order which would stay implementation of the Act pending determination of the merits. The court heard all counsel and signed the order[6] setting oral argument for Friday, April 6, 1973.

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[5] Counsel for plaintips George Patient, et al., petitioned this court on April 3, 1973 to intervene in the principle action. There being no objection by counsel in the *Roe* action, the motion was granted on April 6, 1973 and reference to "plaintiffs" hereinafter includes the intervenors.

[6] The temporary restraining order did not enjoin the implementation of the entire act. Rather it ordered, in substance, that the defendant was restrained from:

1. filing or processing prescription forms identifying the patients receiving Schedule II drugs;

2. requiring physicians or pharmacists from filing prescription forms identifying the patients receiving Schedule II drugs;

and ordered that the defendant retain in a secure place any prescription forms received during the pendency of the temporary restraining order.

Plaintiffs make a two pronged attack on the legislation. First, it is argued that the statute is an unconstitutional invasion of the patient's right to privacy, and second, that the statute creates classifications which do not comport with the dictates of the equal protection clause.

I consider first the equal protection argument. The law in this complex area is currently in a state of flux, see, e. g., Gunther, The Supreme Court 1971 Term foreword: In Search of Evolving Doctrine on a Changing Court, 86 Harv. L.R. 1 (1972), as evidenced by such cases as James v. Strange, 407 U.S. 128, 92 S.Ct. 2027, 32 L.Ed.2d 600 (1972); Weber v. Aetna Casualty and Surety Co., 406 U.S. 164, 92 S.Ct. 1400, 31 L.Ed.2d 768 (1972); Stanley v. Illinois, 405 U.S. 645, 92 S.Ct. 1208, 31 L.Ed.2d 551 (1972); Eisenstadt v. Baird, 405 U.S. 438, 92 S.Ct. 1029, 31 L.Ed.2d 349 (1972); and Reed v. Reed, 404 U.S. 71, 92 S.Ct. 251, 30 L.Ed.2d 225 (1971).

The Court of Appeals in this Circuit has recently characterized the appropriate test as "whether the legislative classification is *in fact* substantially related to the object of the statute." Boraas v. The Village of Belle Terre (2d Cir. 1973), 476 F.2d 806 at 814.

Applying this test I find no constitutional infringement that can be said to pose a substantial federal question. It is of course true, that patients legitimately receiving Schedule II drugs are treated differently than those who are either receiving Schedule III, IV or V drugs, those receiving no drugs at all, or those who are classified as addicts. But this is only improper if the treatment afforded Schedule II users does not substantially further the ends of the statute.

It is rarely easy to pinpoint with precision a statute's "purposes." Here the goal is obviously at least in part to control certain illegal drug uses by doctors, pharmacists

and patients. The plaintiffs intimate that the more lenient reporting standards required of Schedules III, IV and V users make the statute underinclusive and therefore void. This conclusion however results from a misstatement of purpose rather that a defect in the statute. As explained in the Memorandum of Assemblyman Chester Hardt, Chairman of the Temporary State Commission to Evaluate the Drug Laws, the state, by choosing to rely on voluntary and virtually unreviewed compliance with the law as it pertains to the less dangerous drugs of Schedules III, IV and V, sought not only to control drugs effectively but also to limit the intrusion into personal affairs. Thus restricting the new reporting requirements to Schedule II users in fact was consonant with the legislative goals.

The plaintiffs also contend that the statute, by imposing stricter confidentiality requirements to an addict's records[7] than it does to the records of a Schedule II drug user,[8] is

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[7] "§ 3356 Central registry confidentiality.

1. The department shall establish a central registry as part of which the following information shall be assembled:

(a) the name and other identifying data relating to each reported addict;

(b) the status of each addict awaiting admission to an approved program or programs;

(c) the status of each addict in an approved program.

2. Identifying data in such registry with respect to an individual addict shall be available only to a practitioner attempting to ascertain the status of an addict seeking treatment with him or admission to a program with which he is associated."

[8] "§ 3371 Confidentiality of certain records, reports, and information.

1. No person, who has knowledge by virtue of his office of the identity of a particular patient or research subject, a

(*footnote continued on following page*)

irrational and unconstitutional. The Controlled Substances Act deals at some length with distributions of drugs to addicts, Title V, §§ 3350-3356, and attempts to make provision for the effective treatment and rehabilitation of addicts in "maintenance programs." It is well known that addicts have generally been quite reluctant to participate in drug programs. One can well assume that active police surveillance of these programs would generate additional hostility among the addict population. The legislature, recognizing that addicts would be particularly reluctant to join treatment programs if their records were available to the police, imposed especially rigid confidentiality standards for addicts' files. It is evident, therefore, that § 3356 rationally promotes a valid and legitimate state interest and that the differing treatment afforded Schedule II users and addicts does no violence to any strictures imposed by the equal protection clause.

The only remaining question is whether the system devised does in fact further the objectives of the statute. The

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(*footnote continued from preceding page*)

manufacturing process, a trade secret or a formula shall disclose such knowledge, or any report or record thereof, except:

(a) to another person who by virtue of his office is entitled to obtain such information; or

(b) pursuant to judicial subpoena or court order in a criminal investigation or proceeding; or

(c) to an agency, department of government, or official board authorized to regulate, license or otherwise supervise a person who is authorized by this article to deal in controlled substances, or in the course of any investigation or proceeding by or before such agency, department or board.

2. In the course of any proceeding where such information is disclosed, except when necessary to effectuate the right of a party to the proceeding, the court or presiding officer shall take such action as is necessary to insure that such information, or record or report of such information is not made public."

conclusion that it does seems unavoidable. Through the use of this system the state will more effectively be able to investigate and control such drug related abuses as forgeries, prescriptions to fictitious persons, patients receiving dangerous drugs from a number of different doctors, and similar activity. Based upon the evidence presented to me, especially the affidavit of Dr. Robert Whalen, Second Deputy Commissioner of the New York State Department of Health and the Interim Report of the Temporary State Commission to Evaluate the Drug Laws, I can only conclude that the system of reporting required by the statute directly and substantially effectuates the state's legitimate interests as expressed by the Act.

The right to privacy, to which I now direct my attention, is more difficult primarily because the issue has only recently clearly emerged as a basic constitutional consideration. It is not necessary here to expound upon the historical antecedents and the current flowering of that right. We are all aware of course that Griswold v. Connecticut, 381 U.S. 479, 85 S.Ct. 1678, 14 L.Ed.2d 510 (1965) solidified privacy's constitutional status and that since that decision numerous extensions of its essence have occurred. See, *e. g.*, United States v. United States District Court, 407 U.S. 297, 92 S.Ct. 2125, 32 L.Ed.2d 752 (1972), Stanley v. Georgia, 394 U.S. 557, 89 S.Ct. 1243, 22 L.Ed.2d 542 (1969) and, to some extent, the recent decisions of Roe v. Wade, 410 U.S. 113, 93 S.Ct. 705, 35 L.Ed.2d 147 (1973) and Doe v. Bolton, 410 U.S. 179, 93 S.Ct. 739, 35 L.Ed.2d 201 (1973).

The case at bar, however, is significantly distinguishable from each of those cases and from any case cited to the court by counsel. The fundamental thrust of this lawsuit might be made clearer by briefly discussing what is *not* involved here.

First, this is not a case where the state has launched a broad scale invasion into the doctor-patient relationship re-

quiring the publication of the entire medical history and treatment record. Indeed, contrary to plaintiffs' suggestion, even the illness for which a Schedule II drug is prescribed need not be revealed.

Second, the statute *on its face* does not permit unrestricted divulgence of even the limited information collected. In fact § 3371 confines disclosure to the extent consistent with the purposes of the Act. I have also been presented with the memorandum of Assemblyman Hardt and the affidavit of Commissioner Whalen, both of whom appear to be taking all necessary steps to maintain the security of the computerized information.

Finally, this is not a case where the plaintiffs have been able to prove actual abuse of the reporting and computerizing process and consequently to argue facial unconstitutionality based upon pragmatic or historical evidence; that is that such process necessarily and inevitably results in abuse.

In order to further appreciate the essence of plaintiffs' privacy argument, it is necessary to consider the status of the law prior to April 1, 1973. Insofar as the issues involved in this lawsuit are concerned, the only effective distinction is that the new statute requires sending a copy of each prescription for Schedule II drugs to Albany to be computerized. Previously prescriptions required the name of the patient, N.Y. Public Health Law § 3301(32) (McKinney 1971) (repealed 1973), the pharmacist was required to keep a copy of the prescription, *Id.* at § 3322, and law enforcement officials had complete access to the druggists prescription files, *Id.* at §§ 3322(1)(c), 3334. In short, the state had the power to learn all that it may now require to be revealed. The only difference is that now the state has developed the means to make effective use of that basic power which remains unchallenged.

Opinion Denying Plaintiff's Motion for an Order Convening a Three-Judge Court, etc.

I must confess, however, that plaintiffs' claims fall upon sympathetic ears. I share with the plaintiffs a deep concern about the ultimate consequences of overzealous data collection and instant data retrieval. I recognize the dangers in a society which permits the government to know the intimacies of its citizens' lives and especially the consequences to those people against whom such information is maliciously or malevolently used. And I realize the potential for individual harm consequent upon errors of fact becoming imprinted upon unforgiving tapes.

Yet computers, computer banks—the new technology—are facts of present day life. Courts can be no more effective than Canute in turning back the tide. It cannot be contended, at least not seriously, that governmental use of this new technology is constitutionally impermissible. And that is the fundamental and basic question which is being raised.

It may well be that courts will be required to establish guidelines and set standards but that is not this case. I do not believe that the United States Constitution proscribes state use of computer lists which contain the names of patients as is provided for under this statute.

The motions for preliminary and permanent injunctions are denied and the temporary restraining order is dissolved. The complaints are dismissed for want of a substantial federal question.

So ordered.

Opinion of United States Court of Appeals.

RICHARD ROE, an infant, by Robert Roe, his parent et al., Plaintiffs-Appellants,
George Patient et al., Intervenors-Appellants,

v.

Hollis S. INGRAHAM, as Commissioner of Health of the State of New York, Defendant-Appellee.

Nos. 947, 948, Dockets 73-1562, 73-1582.

United States Court of Appeals, Second Circuit.

Argued May 4, 1973.

Decided May 24, 1973.

Before FRIENDLY, Chief Judge, HAYS, Circuit Judge, and JAMESON,* District Judge.

FRIENDLY, Chief Judge:

This appeal from an order of the District Court for the Southern District of New York, 357 F.Supp. 1217 dismissing complaints in actions under the civil rights statute, 42 U.S.C. § 1983, as jurisdictionally implemented by 28 U.S.C. § 1343(3), relates to the New York State Controlled Substances Act, N.Y.Laws 1972, ch. 878, amending N.Y. Public Health Law §§ 3300-96, effective April 1, 1973, McKinney's Consol.Laws, c. 45.

The Controlled Substances Act represents a comprehensive effort by the State, aimed primarily at controlling the

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* Of the United States District Court for the District of Montana, sitting by designation.

abuse caused by diversion of lawfully manufactured and prescribed dangerous drugs into unlawful uses. Broadly speaking, the scheme of the statute is to classify each such drug in one of five schedules, see Public Health Law § 3306, depending on the degree of harm its abuse may cause and the extent of its lawful medical uses, with restrictions imposed on distribution of the drug varying in accordance with the schedule in which it is placed. Schedule I lists drugs with a high potential for abuse, for which there is no generally recognized medical use, including certain opiates and opium derivatives, various hallucinogenic substances, and marijuana; § 3330 forbids prescribing any such substance except for strictly limited purposes detailed in Title III. Schedule II lists substances having a high potential for abuse leading to severe psychological or physical dependence, but having accepted medical use in some cases; included in this schedule are such major narcotics as cocaine, concentrated codeine, morphine, Demerol, and other opiates, and the amphetamines. Schedule II drugs may be prescribed and dispensed only in the manner hereafter described. Schedules III, IV and V list other drugs of medical utility having progressively less severe effects on the central nervous system; these may be prescribed and dispensed in less onerous ways unnecessary here to detail.

Plaintiffs' complaints are particularly directed at the procedure established for the prescription of Schedule II drugs. Section 3338(2) directs that, except for emergency oral prescriptions,[1] substances listed in Schedule II may be dispensed only upon an official New York State prescription form. These forms, to be prepared and issued

[1] The procedure for these, detailed in § 3334, ultimately results in the same filing with the Department of Health of a copy of the prescription bearing the name of the patient about which plaintiffs complain.

by the Department of Health in groups of 100, are to be in triplicate and serially numbered, § 3338(1). So far as here relevant, the prescription must contain the name, address and age of the patient; the name, address, registration number, telephone number and handwritten signature of the prescribing practitioner; specific directions for use; and the date upon which the prescription was actually signed, § 3332(2). When the practitioner also dispenses, he must retain the original for five years and file the two copies with the Department of Health not later than the fifteenth day of the month following that in which the substance was delivered, § 3331(6). When dispensing is to be done by a pharmacist, the practitioner must retain a copy for five years, § 3332(4), the pharmacist must retain the original for a like period, and the pharmacist must file a copy endorsed with the date of delivery, the registration number of the pharmacy, and his signature, with the Department of Health not later than the fifteenth day of the month following that in which the substance was delivered, § 3333. The information contained in the prescriptions filed with the Department of Health is afforded some degree of confidentiality by § 3371, which provides:

> 1. No person, who has knowledge by virtue of his office of the identity of a particular patient or research subject, a manufacturing process, a trade secret or a formula shall disclose such knowledge, or any report or record thereof, except:
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> (a) to another person who by virtue of his office is entitled to obtain such information; or
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> (b) pursuant to judicial subpoena or court order in a criminal investigation or proceeding; or
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> (c) to an agency, department of government, or official board authorized to regulate, license or otherwise supervise a person who is authorized by this

article to deal in controlled substances, or in the course of any investigation or proceeding by or before such agency, department or board.

2. In the course of any proceeding where such information is disclosed, except when necessary to effectuate the rights of a party to the proceeding, the court or presiding officer shall take such action as is necessary to insure that such information, or record or report of such information is not made public.

This action against the Commissioner of Health was brought by three infants reeciving prescriptions for medications listed under Schedule II, two physicians who prescribe drugs listed under that schedule, and the Empire State Physicians Guild, Inc. A post-operative cancer patient who receives Hycodan and Percodan, both Schedule II drugs, a woman suffering from migraine who receives Demerol, a physician who prescribes for one of these patients, and the American Federation of Physicians and Dentists were permitted to intervene as plaintiffs and also to file a separate complaint. Alleging that the compelled disclosure to the Department of Health of the identity of patients for whom Schedule II drugs have been prescribed unconstitutionally invades the patient's right to privacy, infringes on the doctor's right to prescribe treatment solely on the basis of medical considerations, and discriminates against persons suffering from certain diseases by requiring their identification to a governmental agency as a condition to receiving medical treatment, plaintiffs sought temporary and permanent injunctive relief and asked that a three-judge court be convened, 28 U.S.C. § 2281, to consider their complaint. An affidavit supporting the application for a temporary restraining order annexed a Memorandum to members of the New York Legislature from the Chairman of the Temporary State

Commission to Evaluate the Drug Laws, which had proposed the New York State Controlled Substances Act. This Memorandum was submitted because, in addition to elaborating the reasons thought to require the strict control of Schedule II substances, it demonstrated that information from the official prescription would be coded into a computer. The report explained that the computer would be asked certain questions at regular intervals. These questions, which "will be formulated at the highest administrative level," would relate to physicians who had "prescribed and dispensed a greater amount of a Schedule II substance than could possibly be justified by the nature of their practice" and to "situations arising from lost or stolen prescriptions." The Memorandum stated, however, that the proposed plan would not "make use of massive print-outs of patients' names," or, indeed, disclose identifying data about any patient "unless, based upon previous reports, it is clear that such patient has been using stolen or forged prescriptions."[2]

The district court issued a temporary restraining order against the Commissioner's accepting for filing or processing forms containing the identity of patients receiving prescriptions for Schedule II drugs or requiring physicians or pharmacists to file such forms, and directing the Commissioner to maintain in a sealed vault such forms as were received. It also set an early hearing on the motion to convene a three-judge court. The State responded with a

[2] The motion for a temporary injunction was also supported by affidavits of parents of the infant plaintiffs, objecting to the names of their children and the medications they are receiving being disclosed to the state and recorded in the state's data bank, and affidavits of physicians asserting that the disclosure requirement would make them reluctant to prescribe, and patients reluctant to accept, Schedule II drugs, thus causing non-medical considerations to interfere with the doctors' determination as to the appropriate medical treatment.

motion to dismiss the complaint. It submitted an affidavit of Dr. Robert Whalen, Second Deputy Commissioner of the Department of Health. This developed the reasons, discussed below, which were thought to require the filing of the prescriptions with the patients' names on them. Dr. Whalen alleged that similar multiple prescription procedures had been in effect in three other states, for considerable periods, with beneficial effects. He also said that the exception in § 3371(1)(a) allowing disclosure "to another person who by virtue of his office is entitled to obtain such information" was "to allow disclosure internally within the Department to those with a controlled substance responsibility." Annexed to his affidavit were a manual of the State Commissioner of Health entitled "Security of Computer Systems," another manual of the State Commissioner of Health dealing generally with confidential information, and a policy statement dealing specifically with security from unauthorized disclosure of information obtained by the Department of Health under the Controlled Substances Act. Relying in part on this affidavit, which the district judge took to demonstrate that the Department of Health was "taking all necessary steps to maintain the security of the computerized information," he found no substantial constitutional question and dismissed the complaint for lack of federal jurisdiction. He continued the temporary restraining order for three days to allow plaintiffs to seek a further stay from this court after filing notice of appeal, and another panel of this court continued so much of it as required the Commissioner to retain prescriptions received in a sealed vault pending an expedited appeal.[3]

[3] It is clear that the modified restraining order does not relieve physicians and pharmacists from performing the duties imposed on them by the statute under attack. The Commissioner is at liberty to announce this if he deems it desirable.

In the face of recent strong advocacy of the abolition of the three-judge court requirement in constitutional cases,[4] a unanimous Supreme Court has just defined the standard permitting a single judge to dismiss a complaint seeking an injunction on the ground of unconstitutionality in the most limiting terms the Court has ever used. In Goosby v. Osser, 409 U.S. 512, 516, 93 S.Ct. 854, 858, 35 L.Ed.2d 36 (1973) it said:

> Section 28 U.S.C. § 2281 does not require the convening of a three-judge court when the constitutional attack upon the state statutes is insubstantial. "Constitutional insubstantiality" for this purpose has been equated with such concepts as "essentially fictitious" Bailey v. Patterson, 369 U.S. 31, 33, 82 S.Ct. 549, 551, 7 L.Ed.2d 512 (1962), "wholly insubstantial," *ibid,* "obviously frivolous," Hannis Distilling Co. v. Baltimore, 216 U.S. 285, 288, 30 S.Ct. 326, 327, 54 L.Ed. 482 (1910), "obviously without merit," Ex parte Poresky, 290 U.S. 30, 32, 54 S.Ct. 3, 4-5, 78 L.Ed. 152 (1933). The limiting words "wholly" and "obviously" have cogent legal significance. In the context of the effect of prior decisions upon the substantiality of constitutional claims, those words import that claims are constitutionally insubstantial only if the prior decisions inescapably render the claims frivolous; previous decisions which merely render claims of doubtful or questionable merit do not render them insubstantial for the purposes of 28 U.S.C. § 2281. A claim is insubstantial only if "its unsoundness so clearly results

[4] See Report of the Study Group on the Caseload of the Supreme Court 28-30 (1972); 1970 Report of the Proceedings of the Judicial Conference of the United States, at 78-79; Burger, The State of the Federal Judiciary—1972, 58 A.B.A.J. 1049, 1053 (1972).

from the previous decisions of this court as to foreclose the subject and leave no room for the inference that the question sought to be raised can be the subject of controversy." Ex parte Poresky, *supra,* 290 U.S. at 32, 54 S.Ct., at 4; see also Levering and Garrigues Co. v. Morrin, *supra,* 289 U.S. 103, 105, 53 S.Ct. 549, 550, 77 L.Ed. 1062 (1933); Hannis Distilling Co. v. Baltimore, *supra,* 216 U.S. at 288, 30 S.Ct. at 327; McGilvra v. Ross, 215 U.S. 70, 80, 30 S.Ct. 27, 31, 54 L.Ed. 95 (1909).

Despite the severity of this standard, we should have little difficulty in sustaining the district court if plaintiffs' attack had been limited to the discrimination between the disclosure requirements applicable to prescriptions for drugs in Schedule II and those applicable to drugs in Schedules III, IV and V. It is apparent that the limitation of the central filing requirement to Schedule II drugs was designed for the specific purpose of confining the resulting intrusion into privacy to those drugs whose unlawful distribution entails the greatest danger to patients and the public. The legislative purpose in making the differentiation being thus permissible, indeed, laudable, the courts will not assume the task, for which they are conspicuously unfitted, of inquiring whether every drug was properly placed by the Legislature in one schedule rather than another. Lindsley v. Natural Carbonic Gas Co., 220 U.S. 61, 78-79, 31 S.Ct. 337, 55 L.Ed. 369 (1911); Metropolis Theater Co. v. City of Chicago, 228 U.S. 61, 69-70, 33 S.Ct. 441, 57 L.Ed. 730 (1913). The district court likewise was clearly correct in dismissing the plaintiffs' claim that the Act's imposition of stricter confidentiality requirements upon the records of addicts participating in drug maintenance programs than on the information relating to Schedule II drug prescriptions denied them equal protection of

the laws. As the district judge pointed out addicts have understandably been reluctant to bring their drug use to the light of day, and the state could reasonably have believed that only the strictest confidentiality, including protection from disclosure to law enforcement authorities, would encourage them to join treatment programs.

This, however, was only a part, indeed a relatively minor part, of plaintiffs' complaints. The patients' main attack is that the requirement of filing with the Department of Health is an impermissible invasion of a constitutional right to privacy with respect to the status of their health and the medical treatment they are receiving, and the physicians contend that the danger of disclosure impairs a constitutional right to make their decisions solely on the basis of medical considerations.[5]

The concept that privacy may be a constitutional right enjoying protection against governmental intrusions other than those banned by specific provisions of the Bill of Rights, notably the First and Fourth Amendments, see Stanley v. Georgia, 394 U.S. 557, 564-566, 89 S.Ct. 1243, 22 L.Ed.2d 542 (1969); Katz v. United States, 389 U.S. 347, 351-353, 88 S.Ct. 507, 19 L.Ed.2d 576 (1967), was first explicitly stated in Griswold v. Connecticut, 381 U.S. 479, 85 S.Ct. 1678, 14 L.Ed.2d 510 (1965).[6] That decision, along with Eisenstadt v. Baird, 405 U.S. 438, 92 S.Ct. 1029, 31 L.Ed.2d 349 (1972), can be viewed as forecasting recogni-

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[5] The standing of the physicians seems to be established by Griswold v. Connecticut, 381 U.S. 479, 481, 85 S.Ct. 1678, 14 L.Ed. 2d (1965), and Doe v. Bolton, 410 U.S. 179, 185, 93 S.Ct. 739, 35 L.Ed.2d 201 (1973). However, since their claims are less impressive than those of the patients, we will confine our discussion of the merits to the latter.

[6] There are passages in Skinner v. Oklahoma ex rel. Williamson, 316 U.S. 535, 536, 541 (majority opinion of Douglas, J.), 546-547, 62 S.Ct. 1110, 86 L.Ed. 1655 (concurring opinion of Jackson, J.) (1942), which may be regarded as harbingers.

tion of a constitutional right of men and women to decide, free of governmental interference, whether to minimize the risks of conception from sexual intercourse, although *Griswold* focused on the provision of the Connecticut statute proscribing the *use* of contraceptives and the attendant horrors of enforcement in the case of married persons, 381 U.S. at 485-486, 85 S.Ct. 1678, and *Eisenstadt* was rested on the equal protection clause. Roe v. Wade, 410 U.S. 113, 152, 93 S.Ct. 705, 35 L.Ed.2d 147 (1973), went further and held that a woman's right to terminate her pregnancy was a "fundamental" constitutional right, subject to regulation only on the basis of a "compelling" state interest, which was found not to exist during the first trimester and to exist only in a limited degree in the second. Doe v. Bolton, 410 U.S. 179, 93 S.Ct. 739, 35 L.Ed.2d 201 (1973), took a still further step by recognizing a pregnant woman's constitutional right to make the abortion decision on the basis of advice from her own physician without the approval of a hospital committee or the concurrence of other doctors.

Although, as we recently indicated in Rosenberg v. Martin, 478 F.2d 520, at 524 (2 Cir. 1973), the right to privacy which thus far has been granted constitutional protection relates only to "the most intimate phases of personal life," having to do with sexual intercourse and its possible consequences, it is not "obvious" that the right will be thus confined. Indeed, the Court's recognition in Roe v. Wade, *supra,* 410 U.S. at 153, 93 S.Ct. at 727, that the right to privacy is "founded in the Fourteenth Amendment's concept of personal liberty and restrictions upon state action" itself suggests that the right may not be so closely cabined. See, for an adverse criticism, Ely, The Wages of Crying Wolf: A Comment on Roe v. Wade, 82 Yale L.J. 920 (1973). As Mr. Justice Stewart stated in his concurrence in *Roe,* 410 U.S. at 169, 93 S.Ct. at 735, quoting Mr. Justice Harlan's dissenting opinion in Poe v. Ullman, 367 U.S. 497, 543, 81 S.Ct. 1752, 6 L.Ed.2d 989 (1961), the

liberty guaranteed by the due process clause "is a rational continuum which, broadly speaking, includes a freedom from all substantial arbitrary impositions and purposeless restraints, . . . and which also recognizes, what a reasonable and sensitive judgment must, that certain interests require particularly careful scrutiny of the state needs asserted to justify their abridgement."

If there is anything "obvious" about the constitutional right to privacy at the present time, it is that its limits remain to be worked out in future cases. Should the constitutionally protected zone of privacy be extended beyond the area already recognized, the individual's interest in keeping to himself the existence of his physical ailments[7] and his doctor's prescriptions for them would lie rather close in the continuum.[8] If New York had passed a statute directing that all prescriptions, or even all prescriptions for Schedule II drugs, must be published in the press, we do not think the State would have seriously contended, still less that the district judge would have held, that a constitutional attack was "obviously frivolous." That is enough to show that the quetsion whether the right of privacy here asserted by the patients does enjoy some degree of constitutional protection is a substantial one. As-

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[7] While the State correctly points out that the prescription form does not require a description of the illness, plaintiffs counter that, at least for some of the drugs in Schedule II, many members of the public know the ailments for which such drugs are commonly prescribed. To take perhaps the most obvious examples, most informed people would associate large dosages of Demerol with an ailment causing serious pain. It is immaterial that the ailment usually is not one that should arouse any emotion toward the victim save sympathy; most people simply do not want their ailments to be generally known.

[8] Indeed, there is language in Doe v. Bolton, *supra,* 410 U.S. at 194, 93 S.Ct. 739, from which it could be argued that the Court has already taken the step of extending constitutional protection to the privacy of the doctor-patient relationship.

suming that such a constitutionally protected right does exist, the plaintiffs have raised a further question whether the impairment of that right was justified by some larger interest which the State is entitled to pursue.

The right to privacy in matters such as those here at issue surely is not absolute. This is shown by the rulings in Roe v. Wade, *supra,* 410 U.S. at 152, 93 S.Ct. 705, permitting restrictions on the abortion decision during the second trimester of pregnancy and prohibition of it during the third. Also, we do not read the portion of Doe v. Bolton, *supra,* 410 U.S. at 198, 93 S.Ct. 739, striking down Georgia's "two doctor concurrence" requirement as meaning that a state is wholly without power to regulate the practice of medicine or the activities of physicians except by professional censure, deprivation of licenses, or enforcement of the criminal law. Indeed, plaintiffs seem to concede that their constitutional rights were not violated by the previous New York laws, which required prescriptions for narcotic drugs to bear the full name and address of the patient, and the name, address, registration number and signature of the physician, former Public Health Law § 3301(32) (McKinney 1971); required pharmacists to retain copies of prescriptions for two years, former Public Health Law § 3322(1)(c); and allowed inspection of them by state and federal law enforcement authorities as well as the Department of Health, former §§ 3322(1)(c), 3334(1).

New York has advanced powerful arguments in support of the requirement of central filing of prescriptions for Schedule II drugs. The most important are that only by such filing, now complemented by the computer's ability to answer appropriate inquiries, can the State readily detect a number of serious abuses—the same patient going from doctor to doctor and thereby obtaining quantities of Schedule II drugs greater than his legitimate medical needs; over-prescription by doctors; and the theft or

forgery of prescriptions. Each of these abuses leads to an individual's possession of quantities of these dangerous drugs which would be seriously harmful if used and afford the opportunity for sale into illicit drug channels. Without questioning the seriousness of the problem, plaintiffs respond that these abuses could be adequately controlled without central filing, or by central filing without patient's names, and that the added efficiency is not worth the price in terms of risk of disclosure.

On this last point something turns on how great the risk is. While the Constitution does not condemn a state to using ineffective means in dealing with a problem as serious as the use of the opiates and stimulants listed in Schedule II, it may well condition use of a more effective means which involves a danger to constitutionally-protected privacy on the taking of all reasonable precautions to limit the risk. The complaints, and other material of which we may take judicial notice, are not conclusive on this score. Although Dr. Whalen may be correct in asserting that § 3371(1)(a) was intended only to allow disclosure of prescription information to Department of Health officials working in the area, the statutory language is so open-ended that full exploration of how confidentiality is in fact being preserved may be required. If it were clear that the State had taken or proposed to take effective steps, by regulation or otherwise, to limit access to the patients' names on the prescription forms as rigidly as is consistent with accomplishment of the asserted statutory purpose, the grounds for constitutional attack might disappear. But the district court was not entitled to dismiss the complaint on the basis of the State's assertions that it has already done this. The Supreme Court stated long ago in Ex parte Poresky, 290 U.S. 30, 32, 54 S.Ct. 3, 4, 78 L.Ed. 152 (1933), that "The existence of a substantial question of constitu-

tionality must be determined by the allegations of the bill of complaint." See also Goosby v. Osser, *supra,* 409 U.S. at 521, 93 S.Ct. 860 n. 7. Looking at these allegations, and also at the Memorandum of the Temporary State Commission to Evaluate the Drug Laws which was annexed to the moving affidavit of plaintiffs' counsel, and the various state manuals, as we think we may, we do not believe that, under the strict test announced in Goosby v. Osser, *supra,* the complaint could properly have been dismissed without further exploration of the degree of need for central filing including the patients' names on the one hand, and the adequacy of the provisions to protect against malicious or careless disclosure on the other.

The order of dismissal is therefore reversed, with instructions to the district judge to request the convening of a three-judge court under 28 U.S.C. §§ 2281 and 2284. The temporary restraining order, as modified by this court, is continued pending the hearing before such a court and for such further period, if any, as that court may then direct.

Notice of Motion to Dismiss Complaint.

[SAME TITLE]

SIRS:

PLEASE TAKE NOTICE, that upon the annexed affidavit of A. Seth Greenwald, sworn to June 18, 1973, the various summons and complaints, the prior affidavit of Robert P. Whalen, M.D., sworn to April 3, 1973, the proposed regulation on confidentiality, and all the prior submissions and proceedings, the undersigned will move this Court on

June 25, 1973 at 4:30 P.M., in Room , United States Courthouse, Foley Square, New York, New York, for an order pursuant to the Federal Rules of Civil Procedures, Rules 12(b)(6) dismissing the complaints upon the ground that they fail to state a claim upon which relief may be granted, and that they are moot by virtue of the promulgation of the amended regulation 10 NYCRR § 80.107, suspension of any inspection pending determination of this motion, and for such other and further relief as may be just and proper.

Dated: New York, New York
June 18, 1973

Yours, etc.,

LOUIS J. LEFKOWITZ
Attorney General of the
State of New York
Attorney for Defendant
By

.....
A. SETH GREENWALD
Assistant Attorney General

To: SHEA, GOULD, CLIMENKO
& KRAMER, Esqs.

NORWICK, RAGGIO & JAFFE, Esqs.

Affidavit of A. Seth Greenwald, in Support of Motion.

[SAME TITLE]

STATE OF NEW YORK }
COUNTY OF NEW YORK } ss.:

A. SETH GREENWALD, being duly sworn, deposes and says:

I am an Assistant Attorney General in the office of Louis J. Lefkowitz, Attorney General of the State of New York, attorney for defendant.

I have already made objection to plaintiffs' use of fictitious names in this action in my affidavit of April 4, 1973 and reiterate that plaintiffs should be required to disclose their actual identities with any protections the Court considers necessary.

As to any preliminary injunction it should not extend beyond the actual plaintiffs as this is not a class action. In any event no modification of the order of the Court of Appeals is warranted since it is unnecessary.

As to the motion to dismiss, it would appear that there are no issues beyond those presented by the complaint and opposing papers. The defendant has established thorough security it proposes to use with the triplicate prescriptions when the system is implemented, if permitted by this Court. Together with the new regulation, it is submitted that only issues of law are presented by this case and the questions raised by the Court of Appeals are essentially moot.

WHEREFORE, your deponent respectfully requests that the complaint be dismissed.

(Sworn to by A. Seth Greenwald, June 18, 1973.)

Opinion of Three-Judge Court Denying Plaintiffs' and Defendant's Motion.

(36 F. Supp. 536)

Richard ROE, an infant, by Robert Roe, his parent, et al., Plaintiffs,

and

George Patient et al., Intervenors,

v.

Hollis S. INGRAHAM, as Commissioner of Health of the State of New York, Defendant.

No. 73 Civ. 1303.

United States District Court, S. D. New York.

Aug. 23, 1973.

OPINION

ROBERT L. CARTER, District Judge.

I

Statute Under Attack:

This action challenges the constitutionality of certain provisions of the New York State Controlled Substances Act (the "Act"), New York Laws 1972, ch. 878, N.Y. Public Health Law § 3300 et seq. (McKinney's Consol. Laws, c. 45, Supp. 1972) effective April 1, 1973, as amended, New York Laws 1973, ch. 97, ch. 163, ch. 728. The Act attempts a comprehensive regulation of all facets of the legitimate drug trade—research, manufacture, medical prescription, wholesale and pharmaceutical distribution—in an effort to prevent and discover any diversion of this trade to illegitimate use.

The provisions of the Act apply to "controlled substances"—those drugs warranting regulation—which are described in detail in § 3306. Furthermore, that section classifies the regulated drugs into "schedules" depending upon the extent to which the drugs may be lawfully prescribed for medical purposes and the dangers inherent in their misuse. Thus, Schedule I drugs "are all highly abusable substances which have no current medical use or lack accepted safety for use in treatment under medical supervision in this country." Interim Report of the Temporary State Commission to Evaluate the Drug Laws ("Interim Report") at 13.[1] These drugs may not be prescribed, distributed or possessed for any purpose other than the strictly limited use described in Title III, §§ 3324-3329, pertaining to research and related activities, § 3330.

Schedule II contains "those substances which have a high potential for abuse, but also have an accepted or restricted medical use. Abuse of a Schedule II substance may lead to severe physiological dependence." Interim Report at 13. Schedules III, IV and V list those drugs having an accepted medical use but a potential, though in decreasing degree, for psychological and/or physiological dependence consequent to misuse.

The Act requires that an official New York State prescription form[2] be used to prescribe or dispense Schedule

[1] The Temporary State Commission to Evaluate the Drug Laws was created in 1970 to investigate the problems arising under existing drug laws and to recommend changes in the law. New York Laws 1970, ch. 474, as amended by New York Laws 1971, ch. 7. The Committee's recommendations as contained in the Interim Report were adopted by the legislature virtually without modification.

[2] These forms are to be prepared and issued by the Department of Health, numbered serially, prepared in triplicate and issued to practitioners in groups of one hundred at a cost of $10 per group (10¢ per triplicate form), § 3338.

II drugs, § 3338(2)[3], except in cases of emergencies § 3334. This triplicate form must contain the following information: the name, address and age of the patient; the name, address, registration number, telephone number and handwritten signature of the physician, directions for use (*e. g.*, dosage, frequency of dosage and maximum daily use), and date the prescription was signed, § 3332.

In the event the drug is actually administered or dispensed by the prescribing physician, the doctor must retain a copy of the form in his files for a period of five years and file the original and one copy with the Department by the fifteenth day of the month following the month in which the drug was dispensed, § 3331(6). If, however, the prescription is to be dispensed by a pharmacist, the doctor shall keep one copy of the form in his files for a period of five years and deliver to the patient the original and one copy, § 3332(4). The drug user will deliver those two forms to the pharmacist who, upon filing the prescription, shall endorse the original and copy with the date of delivery, the pharmacist's registration number and his signature, § 3333(3). The original of the form will be retained by the pharmacist for five years and the copy must be filed with the Department of Health by the fifteenth day of the month following the month in which in which the drug was dispensed, § 3333(4).

The confidentiality of the records collected pursuant to the above procedures is protected as provided for in the statute, § 3371. That section states:

> 1. No person, who has knowledge by virtue of his office of the identity of a particular patient or research

[3] The statute authorizes the Commissioner of Health to require any particular Schedule III or IV drug to be prescribed or dispensed only upon an official prescription form, § 3338 (3), but the court has no knowledge that such discretionary power has been exercised or that notice of an intention to do has been given and issues concerning these schedules are not before us.

subject, a manufacturing process, a trade secret or a formula shall disclose such knowledge, or any report or record thereof, except:

(a) to another person who by virtue of his office is entitled to obtain such information; or

(b) pursuant to judicial subpoena or court order in a criminal investigation or proceeding; or

(c) to an agency, department of government, or official board authorized to regulate, license or otherwise supervise a person who is authorized by this article to deal in controlled substances, or in the course of any investigation or proceeding by or before such agency, department or board; or

(d) to a central registry established pursuant to this article.[4]

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[4] The statute requires that addict maintenance programs be approved by the Commissioner, § 3352, pursuant to specific statutory standards, § 3353. Such programs are required to maintain certain records pertaining to addicts who are either in or have applied for admission to the program, § 3354 and the program must file monthly reports with the Department summarizing its activity in the preceding month, § 3355. The Department is required to maintain a "central registry" which, by drawing from the reports submitted pursuant to § 3355 and § 3372 (requiring individual physicians to report the name and other identifying information of any person found to be an addict), will be a centralized repository of information pertaining to the status of addicts and applicants for admission to maintenance programs, § 3356. That section provides:

1. The department shall establish or cause to be established a central registry as part of which the following information shall be assembled:

(a) the name and other identifying data relating to each reported addict;

(*footnote continued on following page*)

2. In the course of any proceeding where such information is disclosed, except when necessary to effectuate the rights of a party to the proceeding, the court or presiding officer shall take such action as is necessary to insure that such information, or record or report of such information is not made public.

Pursuant to its statutory authority, the Department of Health has promulgated regulations in respect of confidentiality as follows:

No person who by virtue of his office has knowledge of any records required by article 33 of the Public Health Law or this Part shall disclose such knowledge, or any report or record thereof, except:

(a) to another person who by virtue of his office is entitled to obtain such information;

(b) pursuant to judicial subpoena or court order in a criminal investigation or proceedings; or

(c) to an agency, department of government, or official board authorized to regulate, license or otherwise supervise a person who is authorized by this

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(*footnote continued from preceding page*)

(b) the status of each addict awaiting admission to an approved program or programs;

(c) the status of each addict in an approved program.

2. Identifying data in such registry with respect to an individual addict shall be available only to:

(a) a practitioner attempting to ascertain the status of an addict seeking treatment with him or admission to a program with which he is associated;

(b) an agency, department of government, or commission established pursuant to the mental hygiene law and authorized to gather such information.

> article to deal in controlled substances, or in the course of any investigation or proceeding by or before such agency, department or board. 10 N.Y.C.R.R. § 80.107[5]

The Issue to be Decided:

Although the Act does not specifically so provide, it is alleged by plaintiffs and conceded by the state, that the Department of Health will, upon receipt of the prescription forms, enter the information received into a computer. This anticipated procedure is the focus of plaintiffs' complaint.

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[5] The Attorney General has informed the court that in response to the Court of Appeals decision in this case, discussed below, these regulations were amended to read as follows:

> No person who has knowledge by virtue of his office of the identity of a particular patient or research subject, a manufacturing process, a trade secret or a formula shall disclose such knowledge, or any report or record thereof, except:
>
> (a) to another person who by virtue of his office as an employee of the department is entitled to obtain such information; or
>
> • • • • •
>
> (d) to a central registry established pursuant to this article.

The Act authorizes the Commissioner of Health to promulgate regulations thereunder provided that a 21-day period is allowed for public response, § 3308. Furthermore, New York law requires that a copy of any proposed regulation must be admitted to the legislature at least 21 days before its adoption. N.Y. Executive Law § 101-a (McKinney's Consol.Laws, c. 18, 1972). Immediately after adoption by the Department the regulation must be sent to the Secretary of State for inclusion in the official compilation of rules and regulations. N.Y. Executive Law § 102 (McKinney 1972). We have been advised that the new confidentiality regulation was submitted to the legislature in early June, 1973, and was formally promulgated by the Department of Health on July 2, 1973, effective upon filing with the Department of State.

The original plaintiffs in this action include three infants (by their parents) and one adult receiving Schedule II drugs, two named doctors who prescribe such drugs, and the Empire State Physicians Guild, Inc.[6] The plaintiffs complain of a violation of their constitutionally protected rights, 42 U.S.C. § 1983 and assert that the jurisdiction of the court is founded upon 28 U.S.C. § 1343(3). They allege that the reporting provisions of the Act

> by requiring disclosure of the identity of certain patients . . . invades the patient's right of privacy and confidentiality, infringes on the doctor's right to prescribe treatment for his patients solely on the basis of medical consideration and discriminates against persons suffering from certain diseases by requiring their identification to a governmental agency as a condition to receiving medical treatment for their illness. Complaint, Para. 11.

Shortly after the commencement of the action a post-operative cancer patient and an individual suffering from migraine headaches, both of whom receive Schedule II drugs as medication, the physician prescribing such drugs for one of these patients, and the American Federation of

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[6] The physicians are not here merely asserting the rights of their patients but claim independent violation of protected constitutional rights. Their standing to sue is established by Doe v. Bolton, 410 U.S. 179, 93 S.Ct. 739, 95 L.Ed.2d 201 (1973). See also, Roe v. Ingraham, 480 F.2d 102, (2d Cir. 1973) at n. 5. Although it is unclear from the complaint, the Physicians Guild is apparently suing on behalf of its doctor members. Inasmuch as its claims are only repetitive, we may assume proper standing exists. Griswold v. Connecticut, 381 U.S. 479, 85 S.Ct. 1678, 14 L.Ed.2d 510 (1965), NAACP v. Alabama, 357 U.S. 449, 78 S.Ct. 1163, 2 L.Ed.2d 1488 (1958); Pierce v. Society of Sisters, 268 U.S. 510, 45 S.Ct. 571, 69 L.Ed. 1070 (1925).

Physicians intervened and filed a separate complaint.[7] The intervenor plaintiffs repeat verbatim the language of the original complaint (quoted above) alleging that the Act is constitutionally infirm. In addition, the intervenors claim that the Act

> on its face, conflicts with, is inconsistent with and overlaps federal law and federal regulation and is thus void, being in conflict with the commerce power of the United States government and the laws and regulations enacted by the United States pursuant thereto. Complaint, Para. 13.

Both complaints, in identical laguage, ask for preliminary and permanent injunctive relief and the determination of these issues by a three-judge court pursuant to 28 U.S.C. § 2281.

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[7] All of the patient-plaintiffs—the three children and adult of the original complaint and the intervenor cancer patient and migraine sufferer—are identified in each complaint only by fictitious names ostensibly to protect their identities. This procedure is not explicitly authorized by the federal rules. However, it was given implicit recognition by the United States Supreme Court in Roe v. Wade, 410 U.S. 113, 93 S.Ct. 705, 35 L.Ed.2d 147 (1973) and Doe v. Bolton, 410 U.S. 179, 93 S.Ct. 739, 35 L.Ed.2d 201 (1973). The inherent problems which this procedure poses, most notably the possible inability to fix *res judicata* effect, mandate that it be used sparingly. Here, however, if plaintiffs are required to reveal their identity prior to the adjudication on the merits of their privacy claim, they will already have sustained the injury which by this litigation they seek to avoid. See N.A.A.C.P. v. Alabama, 357 U.S. 449, 78 S.Ct. 1163, 2 L.Ed.2d 1488 (1958). Under such circumstances it is permissible to proceed by pseudonym but only if these fictitious names are actually representative of real and specific aggrieved individuals. Plaintiffs' attorneys have represented to the court that these preconditions have been met.

Prior Court Proceedings:

By Order to Show Cause filed on March 29, 1973, the same date as the filing of the complaint, plaintiffs requested a temporary restraining order enjoining the implementation of the Act which was to become effective on April 1, 1973.

The District Court, after hearing all counsel in chambers, and based upon a number of supporting affidavits and their exhibits, issued a temporary restraining order enjoining the defendant from filing or processing any prescription forms containing a patient's name, from requiring physicians or pharmacists to file such prescription forms with the Department, and requiring placing under seal any form received until dissolution of the order.[8]

On April 6, 1973, the district court heard oral argument on plaintiffs' motion to convene a three-judge court and defendant's motion, made on April 3, 1973, to dismiss the action. The court, D.C., 357 F.Supp. 1217, dismissed for lack

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[8] The order provided that it be:

> ORDERED, that, pursuant to 28 U.S.C. Section 2284(3) and Fed.R.Civ.P.R. 65, pending determination of plaintiffs' application for a preliminary injunction, defendant Hollis S. Ingraham, his agents, servants and employees, be and they hereby are restrained from
>
> (a) accepting for filing or processing New York State prescription forms containing the identity of patients receiving prescriptions for Schedule II controlled substances as set forth in Section 3306 of Article 33 of the Act; and
>
> (b) requiring physicians or pharmacists to file prescription forms containing the identity of patients receiving prescriptions for Schedule II controlled substances as set forth in Section 3306 of Article 33 of the Act; and
>
> it is further ORDERED that defendant, his agents, servants and employees shall retain in a sealed vault or other equally secure place any prescription forms received by them during the pendency of this temporary restraining order.

of a substantial federal question both in respect of the claim of denial of equal protection and infringement of plaintiffs' right of privacy.[9]

The Court of Appeals reversed the order of dismissal. Roe v. Ingraham, 480 F.2d 102 (2d Cir. 1973). While agreeing that plaintiffs' equal protection claims were properly dismissed, the court concluded that "the question whether the right of privacy here asserted by the patients does enjoy some degree of constitutional protection is a substantial one." *Id.* at 108. Assuming that right extended to the circumstances of this case, the district court would be required to determine whether its invasion was justified. Such a determination would require a factual investigation of the "need for central filing including the patients' names on the one hand and the adequacy of the provisions to protect against malicious or careless disclosure on the other." *Id.* at 109. For these reasons the Court of Appeals directed the district judge to request the convening of a three-judge court to make such a determination.

In stating that the plaintiffs' claim was "substantial" the Court of Appeals used that word as applied to the power of a single judge to dismiss a complaint seeking an injunction against an allegedly unconstitutional state law. Its decision means only that the complaints are "substantial" in that they are not "essentially fictitious", "wholly insubstantial", "obviously frivolous". Goosby v. Osser, 409 U.S. 512, 516, 93 S.Ct. 854, 858, 35 L.Ed.2d 36

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[9] The trial court continued the temporary restraining order for three days to permit plaintiffs an opportunity to seek a further stay from the Court of Appeals. That court continued the order only insofar as it required the Commissioner to seal the prescription forms he receives pending appeal. Thus, doctors and pharmacists were required to perform all of their obligations under the Act. This modified order was continued by the three-judge court and remains in effect at this time.

(1973) (citations omitted). Whether the complaints are sufficiently substantial to defeat a motion to dismiss and whether plaintiffs are entitled to a preliminary injunction upon the determination of a statutory court of three judges, are wholly different problems.

II

Hearing Before This Court:

On remand, this statutory court was convened, as provided by 28 U.S.C. § 2281, and on June 25, 1973 heard oral argument on the plaintiffs' motion for a preliminary injunction and defendant's motion to dismiss.

Preliminary Injunction:

In order to prevail on a motion for preliminary injunctive relief, the moving party must demonstrate a clear showing of probable success on the merits *and* the possibility of irreparable injury. Gulf & Western Industries, Inc. v. Great Atlantic & Pacific Tea Co., Inc., 476 F.2d 687 (2d Cir. 1973). However, "where the balance of hardship tips decidedly toward the party requesting the temporary relief", Dino De Laurentiis Cinematograficia S.p.A. v. D-150, Inc., 366 F.2d 373, 375 (2d Cir. 1966), the burden of demonstrating probable success on the merits is reduced *if* the moving party "has raised questions going to the merits so serious, substantial, and difficult as to make them a fair ground for litigation and thus for more deliberate investigation." Checker Motors Corp. v. Chrysler Corp., 405 F.2d 319, 323 (2d Cir.) cert. denied, 394 U.S. 999, 89 S.Ct. 1595, 22 L.Ed.2d 777 (1969), *accord* Exxon Corp. v. City of New York, 480 F.2d 460 (2d Cir. 1973), Gulf & Western Indus. Inc. v. Great Atlantic & Pacific Tea Co., Inc., *supra*.

In order to determine the extent to which plaintiffs' claims measure up to these standards it is obviously necessary to consider, in some depth, the substantive content of the right of privacy.[10]

The Right of Privacy:

The plaintiffs assert that the state's systematic collection of all prescriptions for Schedule II drugs, which by statutory command must contain the patient's name, and the subsequent computerization of this information, violate their constitutionally protected right of privacy. While the Constitution does not specifically proclaim any general right of privacy, certain provisions of the Bill of Rights have been held to confer a guarantee of privacy. As early as 1885 the United States Supreme Court recognized that the Fourth and Fifth Amendments insure "the sanctity of a man's home and the privacies of life." Boyd v. United States, 116 U.S. 616, 630, 6 S.Ct. 524, 29 L.Ed. 746 (1885). Yet, for many years the Court would not go beyond the specific strictures of the Constitution to protect individual privacy.[11]

In Katz v. United States, 389 U.S. 347, 88 S.Ct. 507, 19 L.Ed.2d 576 (1967) in which an electronic listening device was attached to the outside of a telephone booth, the Court abandoned the trespass concept of Fourth Amendment

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[10] In their briefs and on oral argument before the three-judge court plaintiffs abandoned the equal protection claim which they had pressed in the earlier proceedings, and that issue, therefore, is no longer a question in this litigation.

[11] See, *e. g.*, Olmstead v. United States, 277 U.S. 438, 48 S.Ct. 564, 72 L.Ed. 729 (1928), in which the Court concluded that wiretapping is not a "search" within the meaning of the Fourth Amendment. Ultimately, the limitations imposed by *Olmstead* were lightened.

violation and chose instead to protect "the privacy upon which [the individual] justifiably relied." *Id.* at 353, 88 S.Ct. at 512. Even here, however, the protection of an aspect of individual privacy derived not from any general, unspecified rights, but rather, from a specific provision of a guaranteed freedom.

The First Amendment has also been interpreted to encompass certain privacies necessarily included within the scope of its specific mandates. Thus, in NAACP v. Alabama, 357 U.S. 449, 78 S.Ct. 1163, 2 L.Ed.2d 1488 (1958) the Court, in protecting the integrity of the membership lists of a private organization, recognized the "freedom to associate and privacy in one's associations," *id.* at 462, 78 S.Ct. at 1172, which emanates from the guarantees of speech and assembly. Watkins v. United States, 354 U.S. 178, 77 S.Ct. 1173, 1 L.Ed.2d 1273 (1957), in limiting the scope of congressional committee questioning of individuals, made note of the need "to insure that the Congress does not unjustifiably encroach upon an individual's right to privacy nor abridge his liberty of speech, press, religion or assembly." *Id.* at 198-199, 77 S.Ct. at 1185. Similarly, the First Amendment has been held to include a correlative right to receive information and ideas. Thus, the attempt to criminalize the mere private possession of obscene material was found to be unconstitutional. Stanley v. Georgia, 394 U.S. 557, 89 S.Ct. 1243, 22 L.Ed.2d 542 (1969).

These rights of privacy discussed above are only examples of the protection afforded pursuant to specific provisions of the Bill of Rights. The plaintiffs here, however, do not contend their claim is derived from any particular section of the Constitution. Rather, they assert an independent right of privacy first given cognizance by the United States Supreme Court in Griswold v. Connecticut, 381 U.S. 479, 85 S.Ct. 1678, 14 L.Ed.2d 510 (1965). Al-

though sharply divided over the exact origins of such a right, a majority of the Court recognized the existence of a constitutionally protected "zone of privacy" which shielded the individual from unreasonable personal intrusions by federal or state governments. This principle has been reasserted in a number of subsequent cases. See, *e. g.*, Eisenstadt v. Baird, 405 U.S. 438, 92 S.Ct. 1029, 31 L.Ed.2d 349 (1972); Roe v. Wade, 410 U.S. 113, 93 S.Ct. 705, 35 L.Ed.2d 147 (1973); Doe v. Bolton, 410 U.S. 179, 93 S.Ct. 739, 35 L.Ed.2d 201 (1973). Each of these cases involved instances of sexual conduct, and as recently noted in this Circuit, "the right to privacy which thus far has been granted constitutional protection relates only to 'the most intimate phases of personal life' having to do with sexual intercourse and its possible consequences. . . ." Roe v. Ingraham, *supra* 480 F.2d at 107, quoting Rosenberg v. Martin, 478 F.2d 520, 524 (2d Cir. 1973).

Plaintiffs' claims, therefore, raise novel and serious questions with potentially far-reaching consequences as to the permissible reach of the protection afforded by the right of privacy as an independent constitutional guarantee. In order to decide the motion before us, however, we need not, at this time, fully define the limits of that right.

Plaintiffs have conceded the constitutionality of the New York law as it existed prior to the effective date of the Controlled Substances Act. Pursuant to the provisions of that now repealed statute—the Narcotic Drug Control Act, New York Laws 1953, ch. 879, §§ 3300-3366, as amended—all prescriptions were required to bear the patient's name, New York Laws 1961, ch. 206, § 3301(32), the pharmacist dispensing the prescribed drug had to retain the prescription in his file for a period of two years, New York Laws 1953, ch. 879, § 3322, subd. 1(c), and the pharmacist's files had to be maintained "so as to be readily accessible for inspection by any public officer or employee engaged in the enforcement of this article." *Id.*[12]

It is evident, therefore, that the nature of the information required to be revealed by individual legitimate drug users remains essentially the same. Under the old law, however, the accumulation of records began and ended with the individual pharmacist, without any attempt at centralization. Now, of course, although the prescription information remains the same, the data is transmitted to a single data-collection facility. Plaintiffs' complaints, therefore, go only to this centralized collection of information ("record-keeping") rather than to the nature of the information obtained in the first place ("reporting").

This essential distinction between reporting and record-keeping in respect of infringement of constitutional proscriptions was most recently noted in Stark v. Connally, 347 F.Supp. 1242 (N.D.Cal. 1972), appeal pending 41 L.W. 3509 (1973). In that case the plaintiffs challenged the provisions of the Bank Secrecy Act, 31 U.S.C. §§ 1051-1122. The record-keeping provisions of the statute required banks to keep the customary ledger records of individual accounts and microfilm copies of all checks, drafts or other instruments drawn on, presented for payment to, or received for deposit by the bank. The reporting provisions gave the Secretary of the Treasury virtually unlimited power to require the reporting of all business and individual financial transactions, regardless of size.

It was only as to the *reporting* provisions relating to domestic transactions that the court found the statute transgressed constitutional guarantees of privacy, and then only because of the particularly broad discretion given to

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[12] See, also, New York Laws 1953, ch. 879, § 3334 which permitted access to the files by United States officials in regard to enforcement of the federal drug laws.

the Secretary to require submission of information about all aspects of every financial transaction. Thus, *Stark* would support plaintiffs' position here only if the New York State Commissioner of Health had been given broad powers to delve into intimate details of the individual's medical history. In fact, the extent of the reporting provisions, namely, the insertion of the patient's and doctor's names on a prescription, are here not deemed offensive, and thus *Stark* supports defendant's contention that the Act does not unconstitutionally encroach upon plaintiffs' right of privacy.

Equally important for the defendant is Thom v. New York Stock Exchange, 306 F.Supp. 1002 (S.D.N.Y. 1969), affd. 425 F.2d 1074 (2d Cir.), cert. denied 398 U.S. 905, 90 S.Ct. 1696, 26 L.Ed.2d 64 (1970). There plaintiff challenged a New York law requiring all persons employed by member firms of national security exchanges to be fingerprinted as a condition of employment, N.Y. General Bus. Law § 359-e(12) (McKinney's Consol. Laws, c. 20, Supp. 1972), claiming that the statute was, *inter alia,* an unconstitutional invasion of his right to privacy. The court noted that the plaintiff did not contest the state's right to investigate employees of national security firms but only objected to being fingerprinted.

> But fingerprinting under the statute is only a means of verifying the required information as to the existence or nonexistence of a prior criminal record. It involves no additional intrusion into the personal lives of the employees and applicants. The submission of one's fingerprints is no more an invasion of privacy than the submission of one's photograph or signature to a prospective employer, which the Stock Exchange rules still require. *Id.* at 1009 (Footnote omitted.)

Thom emphasizes once again the underlying fallacy of plaintiffs' argument. Any invasion of privacy which occurs under this statute would appear to result from the original insertion of a patient's name on the prescription and its delivery to the pharmacist rather than the subsequent centralized collection of these documents. Furthermore, the plaintiffs have been unable to produce any evidence, either by affidavit, scientific study, official document or otherwise, which provides even the slightest hit of actual, or even likely, injury which will result to the plaintiffs if the drug reporting system becomes operational.[13] Indeed, the

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[13] The plaintiffs argue that the very act of coding a patient's name into a centralized computer would result in the unwarranted invasion of a constitutionally protected right to privacy. At oral argument this proposition was supported primarily by counsel's reference to the general threat of privacy posed by ever-increasing capacity of data-collection systems and computer informational transfer on the one hand, and the more specific harm flowing to particular individuals consequent to the perpetuation of incorrect data and the unauthorized divulgence of private information.

Plaintiffs' fears are shared by many and have within the last few years generated considerable literature. The seminal work is Westin, "Privacy and Freedom" (1967) in which the author, as Chairman of the Special Committee on Science and Law of The Association of the Bar of the City of New York, first defined privacy as "the claim of individuals, groups, or institutions to determine for themselves when, how, and to what extent information about them is communicated to others." *Id.* at 7. After examining the "new tools for invading privacy" he concludes that the governing institutions of our society have been remiss in maintaining the balance of privacy in this country and that without immediate action we are threatened with subjugation to the tools of science. Interestingly enough, Westin, five years later, has coauthored, as Project Director of the Project on Computer Databanks of the Computer Science and Engineering Board of the National Academy of Sciences, the only thorough study of the actual manner in which operating computer systems have influenced individual privacy. Westin and Baker, "Databanks in the Free

(*footnote continued on following page*)

Memorandum of Assemblyman Chester Hardt, Chairman of the Temporary State Commission to Evaluate the Drug Laws, to Members of the Legislature, which was submitted as an exhibit to *plaintiffs'* moving papers, reflects favorably on defendant's position. This memorandum, along with the Interim Report and the affidavit of Dr. Robert Whalen, Second Deputy Commissioner of the New York State Department of Health, all demonstrate 1) that the state perceives itself to be in the throes of a crisis situation resulting from the rampant illegal use of drugs; 2) that the diversion of legal drugs to illicit use is a substantial contributing factor in this dangerous situation; 3) that the responsible state officials have engaged in serious, protracted and extensive study and research, including the solicitation of advice and recommendations from various representatives of special interest groups and the public at large, all of which resulted in the proposed legislation; and 4) that the methods ultimately decided upon appear on their face to be reasonably calculated to effectuate the purposes for which they were established, namely, to effectively monitor the ebb and flow of the legal drug trade so as to identify sources and methods of diversion.[14]

(*footnote continued from preceding page*)

Society: Computers, Record-Keeping and Privacy" (1972). This study, like its predecessor, does not make light of the awesome capabilities of the computers. Yet, it concludes that: "Our finding is that [the earlier prediction that computers would destroy practical boundaries of privacy] does not fit the computerized record systems in existence in 1970-72." *Id.* at 243.

[14] Plaintiffs argue that other states have adopted less restrictive legislation which does not require the centralized collection of patients' names. The validity of the New York law is not undercut by the existence of different laws elsewhere, particularly when the enactment of the instant statute was preceded by extensive research and study which demonstrates the state's attempt to construct a statutory scheme responsive to local needs.

The constitutional right of privacy, obviously, is not an absolute bar to all government action that intrudes into one's personal life. The critical question is whether the objective which the regulation seeks to accomplish is necessitated by a subordinating state interest justifying the degree and consequences of the resulting personal instrusion. See, *e. g.*, Roe v. Wade, *supra*, 410 U.S. at 153, 93 S.Ct. at 727; Roe v. Ingraham, *supra* 480 F.2d at 108. In seeking a preliminary injunction the burden is on the plaintiffs to demonstrate a probability of success or at least the existence of a serious and substantial question warranting further deliberation. Robert W. Stark, Inc. v. New York Stock Exchange, 466 F.2d 743, 744 (2d Cir. 1972), Inmates of Attica v. Rockefeller, 453 F.2d 12 (2d Cir. 1971).

In order to obtain preliminary injunctive relief, the plaintiffs are bound to show, at the very least, a substantial legal foundation for their claim that the reporting provisions of the statute violate their right of privacy *and* that the consequences of the resulting intrusions are not justified when considered against the state's interest. However, the plaintiffs have not produced any evidence which demonstrates conclusively, or even supports inferentially, the conclusion that, assuming the right to privacy will be extended to cover this case, the competing interests of the state are not sufficient to overcome whatever injury they may suffer. It is this lack of proof which, at this stage of the proceedings, causes plaintiffs' success on the merits to be insufficiently probable and their claim to be decidedly insubstantial.

Having reached this conclusion, it is not necessary to decide the question of irreparable injury or tipping of the balance of hardships. It should be noted, however, that the state's efforts are directed against a very real and pressing emergency requiring immediate and effective re-

sponse. The injury to the state and its people resulting from any delay in implementation of programs designed to deal with this problem may be quite significant. On the other hand, there is no evidence of any immediate injury threatening the plaintiffs other than the computerization of their names at the Department of Health and even this injury is easily susceptible to remedy, should the plaintiffs ultimately prevail, merely by ordering the state to destroy its records and erase the tapes.

Motion to Dismiss:

The defendant's motion to dismiss, subject as it is to the most favorable reading of plaintiffs' complaint, cannot be sustained. The discussion above demonstrates only that at this time the plaintiffs have not met the heavy burden required to convince this court of the propriety of a preliminary injunction. On the other hand, the plaintiffs ought to be allowed to explore more fully the outer reaches of the right to privacy itself and to submit the necessary intensive and detailed analysis of the competing interests of the state and the individual. Specifically, the plaintiffs must be afforded the opportunity to demonstrate that the computerization of names is not necessary for the accomplishment of the state's goals, that the controls developed by the state are inadequate to protect against unauthorized disclosure of the computerized information and that the injury to the plaintiffs resulting from the implementation of this system of centralized filing is sufficiently serious to overcome any competing state interest.

The motion to dismiss is denied. The motion for preliminary injunction is denied and the restraining order heretofore entered is vacated.

So ordered.

Answer.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

RICHARD ROE, an infant, by ROBERT ROE, his parent, et al.,
Plaintiffs,

against

HOLLIS S. INGRAHAM, as Commissioner of Health of the State of New York,
Defendant.

73 Civ. 1303

GEORGE PATIENT, et al.,
Intervenors,

against

HOLLIS S. INGRAHAM, as Commissioner of Health of the State of New York,
Defendant.

73 Civ. 1431

Defendant for his answer to the complaints herein, respectfully alleges:

As to 73 Civ. 1303

FIRST: Denies as to paragraph "1" that plaintiffs bring this action "on behalf of all others similarly situated . . ." There is no request pursuant to Rule 23 for a class action order.

Answer.

SECOND: Denies knowledge or information sufficient to form a belief as to paragraphs "3", "4" and "5".

THIRD: Denies knowedge or information sufficient to form a belief as to paragraph "6" except as otherwise appears from the records of the Secretary of State of the State of New York.

FOURTH: Denies so much of paragraph "9" as to physicians' dispensing, Public Health Law § 3331(6) since the statute has been amended; and as to P.H.L. § 3371(1)(a), in that regulations have been issued by defendant further regulating disclosure of confidential information.

FIFTH: Denies each and every allegation contained in paragraphs "11", "12" and "13". As to "12", the action involves a hypothetical state of fact, contemplating improbable violations of law and statute.

As to 73 Civ. 1431

SIXTH: Denies as to paragraph "1" that plaintiffs bring this action "on behalf of others similarly situated . . ." There is no request pursuant to Rule 23 for a class action order.

SEVENTH: Denies so much of paragraph "2" which alleges jurisdiction pursuant to 28 U.S.C. 1331, the Commerce Clause, U.S. Const., Cert. 1, § 8.

EIGHTH: Denies as to paragraph "3" that the amount in controversy is in excess of $10,000.

NINTH: Denies knowledge or information sufficient to form a belief as to paragraphs "4", "5", "6" and "7".

Answer.

TENTH: As to paragraph "10", see paragragh "FOURTH" herein.

ELEVENTH: Denies paragraphs "12" and "13".

As to both actions—for a first separate and complete defense

TWELFTH: The plaintiffs fail to present an actual case or controversy.

For a second separate and complete defense

THIRTEENTH: The complaint(s) fail to raise a substantial question within the jurisdiction of this Court.

For a third separate and complete defense

FOURTEENTH: The complaint(s) fail to state a claim upon which relief may be granted.

For a fourth separate and complete defense

FIFTEENTH: The need for filing of the specified official prescriptions is established by the legislative history and such a determination is solely within the discretion of the legislature. A court cannot look behind or review this discretion.

SIXTEENTH: The State has a legitimate interest in protecting public health to require filing. Hypothetical injury to plaintiffs is inadequate to overcome this interest.

Answer.

FOR A FIFTH SEPARATE AND COMPLETE DEFENSE

SEVENTEENTH: The statute itself and regulations promulgated by defendant are adequate to protect against unauthorized disclosure of computerized information, assuming any right of privacy applies to prescriptions.

EIGHTEENTH: Unauthorized disclosure is a violation of criminal statutes and not to be presumed.

WHEREFORE, it is respectfully requested that the complaint(s) be dismissed.

Dated: New York, New York
September 26, 1973

LOUIS J. LEFKOWITZ
Attorney General of the
State of New York
By

s/ .....
A. SETH GREENWALD
Assistant Attorney General
Attorney for Defendant

Stipulation (Legislative History).

[SAME TITLE]

IT IS HEREBY STIPULATED AND AGREED by and between the undersigned that, for purposes of the above entitled action, the following documents constitute the legislative history of the sections in Article 33 of the Public Health Law at issue herein:

1. Reporting of Sales of Dangerous Drugs, Second Interim Report of the Temporary State Commission to Evaluate the Drug Laws (Albany, N.Y. April 5, 1971);

2. Proposed New York State Controlled Substances Act and Revision of the Penal Law, Interim Report of the Temporary State Commission to Evalulate the Drug Laws (State of New York—[1972] Legislative Document No. 10); and

3. Memorandum of Chester R. Hardt, Chairman of the Temporary State Commission to Evaluate the Drug Laws (Appendix to Court of Appeals, pp. 40a-44a).

and

IT IS FURTHER STIPULATED AND AGREED that the foregoing is without prejudice to the right of any party to offer tapes,

Stipulation (Legislative History).

transcripts, exhibits or other material referred to in the document described in paragraph "2" hereinabove.

Dated: New York, New York
June 20, 1974

SHEA GOULD CLIMENKO & KRAMER

By MICHAEL LESCH
A Member of the Firm

and

SOLOMON Z. FERZIGER, Esq.

Attorneys for Plaintiffs

LOUIS J. LEFKOWITZ, Esq.
Attorney General

By .....
Assistant Attorney General
Attorney for Defendant.

SO ORDERED:

.....
U. S. D. J.

Chester Hardt Memorandum.

STATE OF NEW YORK

TEMPORARY STATE COMMISSION

TO

EVALUATE THE DRUG LAWS

STATE CAPITOL, ROOM 250
ALBANY, NEW YORK 12224
(510) 472-8511

TO: MEMBERS OF THE LEGISLATURE

FROM: Chester R. Hardt, Chairman

RE: TRIPLICATE PRESCRIPTIONS; NEW YORK STATE CONTROLLED SUBSTANCES ACT; EFFECTIVE APRIL 1, 1973.

Many of you have received communications from medical practitioners concerning the New York State Controlled Substances Act particularly the triplicate prescription requirement for Schedule II Substances. To assist you in replying, I have prepared the enclosed memorandum which should enable you to respond to these inquiries.

If my office can be of further assistance to you, please let us know.

The triplicate prescription provision is but one facet of the comprehensive system of control against diversion of lawfully manufactured, distributed, prescribed and dispensed psychoactive drugs enacted by the Legislature and the Governor in 1972. Public Health Law licensing provisions have been tightened, specific rules regarding safeguards for dispensing methadone have been enacted, and greater preventive enforcement authority has been given to the State Health Department.

The triplicate prescriptiton concept was first proposed by our Commission in its Interim Report of April 5, 1971. Initial reaction appeared favorable, and the Commission proposed triplicate prescriptions as part of the system to control the illicit flow of drugs with a medical use in its next draft report, circulated to medical societies and all interested parties throughout the State in September of 1971. Hearings were held in major cities, and both invited and volunteer speakers were heard from every aspect of every discipline involved. Alternative proposals were actively solicited. The reaction of all of the experts, most of the laymen, and all of the government agencies contacted was that voluntary cooperation to stem the tide of illicit therapeutic drug traffic was not possible in this State.

However, when all of the evidence was in, the Commission did not recommend that all dangerous drugs require a triplicate prescription. We believed, and we still believe, that there continues to be room for voluntary curtailment of the prescribing and dispensing of controlled substances, particularly the short-acting barbituates, which are still in Schedule III. We believe that if the terrible epidemic of short-acting barbituate abuse in Southern California is averted in New York State, the triplicate prescription provision will not be extended to these substances. With regard to those drugs now in Schedule II, however, such as morphine and amphetamines, the evidence at our hearings was clearly that if we did not already have an epidemic with these drugs, we were on the threshold of one.

At the outset, multiple prescriptions will be required only for Schedule II substances. These include the major narcotics, such as pure opium, pure codeine, morphine, Demerol and Dilaudid. Also included are the amphetamines, including methamphetamine, and amphetamine-like substances, such as Ritalin and Preludin. There is a

likelihood at this time that methaqualone (Quaalude) will also be included. Subject to exception from the multiple prescription requirement will be certain compounds containing amphetamines whose other ingredients vitiate the stimulant effect of the amphetamines. These substances represent a small fraction of the drugs dispensed or prescribed in the usual course of a physician's practice.

This requirement was conceived, by the Legislature and the Governor, as an integral part of the Controlled Substances Act. The reason is that the relationship between prescribing practices and general patterns which create a climate hospitable to drug abuse has been firmly established by the overwhelming preponderance of evidence received by our Commission. Up to 30 per cent of all those addicted to heroin since 1970 began their drug abuse by misuse of prescribed medications. The drug dependence and illness resulting from the over-prescribing of stimulants has been documented at every level of government and by nearly all responsible professionals. For example, a recent NIHH study revealed that although general practitioners represent but 30 per cent of all physicians, they account for 41 per cent of all prescriptions for psychoactive drugs. The stimulants, Ritalin and Preludin, were not originally contained in the federal Schedule II. Our Commission petitioned the federal government to include Ritalin and Preludin in their Schedule II, just as we have done in our Schedule II, based upon the experience of almost uncontrollable abuse of these amphetamine-like substances in Sweden following the prescription of amphetamines in that country. The Federal government did, indeed, add these substances to their Schedule II at our behest.

Here is how the multiple prescription system will work in New York State. Upon prescribing or dispensing a Schedule II substance, the practitioner will use an official

New York State form instead of a sheet from his usual prescription pad. Official forms will be provided by the New York State Department of Health. If the physician dispenses the substance, he will keep the original and forward two copies to the Department. If he prescribes the substance, he will give or mail to the patient the original and one copy. The patient will take both the original and the copy to the pharmacy. The pharmacist filling the prescription will sign his name upon the original and the copy and will note the date of delivery, and the registration number of the pharmacy. Once a month, he will send his accumulated endorsed copies to the Department. He will retain the original for five years.

Although official prescriptions are not refillable, such a prescription may authorize the dispensing of a maximum 30-day supply of the substance in question. All regular prescriptions for controlled substances in Schedules III, IV and V, including phenobarbital, may be refilled five times in any given six month period of time.

Prescriptions, including official prescriptions, may be mailed to long-term or invalid patients. Telephone prescriptions may be filled for all controlled substances, even for Schedule II narcotics, by phamacists, providing the pharmacist makes a reasonable attempt to verify the identity of the person representing himself to be a doctor, for example, by a callback, and providing that the physician follow up the oral prescription with an official or a written prescription, as the substance in question may require.

The New York State Controlled Substances Act materially tightens restrictions on divulging confidential information. Under present law, confidentiality of patient records simply does not exist with regard to law enforcement personnel who may inspect such records at will. Nothing relating to patient records may be disclosed under the new law, even in the course of a criminal investigation,

except upon a judicial subpoena. Moreover, under the new law measures must be taken in any administrative proceeding, against a practitioner, to seal exhibits and to delete the patient's name.

With regard to data processing techniques that will be used in connection with multiple prescriptions, the system will work as follows: information from the official prescription will be coded into a computer. The prescription copy itself will be kept separately in a coded batch. The batch number will be in the computer. At regular intervals, certain specific questions will be asked of the computer. These questions will be formulated at the highest administrative level and no question may be asked of the computer that has not been previously approved by the Department. The questions will relate to physicians who have prescribed and dispensed a greater amount of a Schedule II substance than could possibly be justified by the nature of their practice. The computer will also be asked to report on situations arising from lost or stolen prescriptions.

It is extremely important that you make note of the fact that, unlike many private health insurance programs that presently employ data processing techniques for determining costs and eligibility of patients, our proposed plan will *not* make use of massive print-outs of patients' names. The computer will not disclose identifying data about any patient unless, based upon previous reports, it is clear that such patient has been using stolen or forged prescriptions.

Law enforcement officials in both California and Illinois have been consulted in considerable depth about the use of multiple prescriptions, since they have been using them for a considerable period of time. They indicate to us that they are not only a useful adjunct to the proper identification of culpable professional and unscrupulous drug

abusers, but that they also give a reliable statistical indication of the pattern of drug flow throughout their states: information sorely needed in this state to stem the tide of diversion of lawfully manufactured controlled substances. Our independent investigation of these systems in California and Illinois has failed to reveal one single case of the invasion of a patient's right to privacy, despite the fact that these other systems make use of massive computer print-outs of patients' names, which we do not.

The people of the State of New York have time and again been demonstrated to be the most susceptible of all the people in the United States to drug abuse. It is the most deeply felt conviction of those involved in helping to curb drug abuse in this state that the multiple prescription requirement will be a safe and useful implement in this effort.

Pre-Trial Order on Consent.

[SAME TITLE]

On October 24, 1974, the attorneys for the parties to this action appeared before the Court at a pre-trial conference pursuant to Rule 16 of the Federal Rules of Civil Procedure and, as a result thereof, the following action has been taken:

I. *Stipulation of Facts*

The parties stipulate that the following facts are not in dispute in this action. Each party reserves the right to object to the materiality of any such stipulated facts and its relevancy to the issues:

A. *Manner In Which The Triplicate Prescription Forms Are Used By Physicians and Pharmacists*

1. Prior to April 1, 1973, the effective date of Article 33 of the Public Health Law and at all times thereafter, prescription forms for Schedule II drugs have been sent to all qualified physicians who ordered such forms.

2. Annexed hereto marked "Exhibit A" is the list of Schedule II drugs which appears in Article 33 of the Public Health Law. Annexed hereto marked "Exhibit B" is a letter from the Commissioner of Health to physicians instructing them how to obtain and use the forms and setting forth a list of some of the drugs, together with their trade names. The Commissioner of Health is authorized to reschedule Schedule III drugs or Schedule IV drugs as Schedule II drugs (see § 3338(2)), but

no such re-schedulings had been made as of February 11, 1974. There has been statutory reclassification. (See Chapter 97, Laws of 1973, a copy of which is annexed hereto marked "Exhibit "C".)

3. Acting under Article 33 of the Public Health Law, the Department of Health requires a physician dispensing a Schedule II drug to keep one copy of the prescription and mail the original and remaining copy in a pre-addressed envelope provided by the State of New York State Department of Health, Bureau of Controlled Substances, Licensing and Evaluation, 845 Central Avenue, Albany, New York 12206. A physician who only prescribes the drug but who does not dispense is required to keep one copy of the prescription form and give the original and copy to the patient, who must take them to a pharmacist in order to have the prescription filled. The pharmacist is required to keep the original prescription form and to send the remaining copy to Albany. (See §§ 3337 and 3333.)

4. The copy of the prescription form that is sent to Albany contains (a) the name, address, telephone number and BNDD number (now known as DEA number)* of the prescribing practitioner, (b) the date on which the prescription was issued, (c) the name, age and address of the patient, (d) the name and amount of the drug prescribed, (e) the maximum daily dosage thereof, (f) the signature of the practitioner, (g) the prescription number issued by the pharmacy, (h) the date the prescrip-

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*"BNDD number" refers to the number given by the Federal Bureau of Narcotics & Dangerous Drugs ("BNDD"), now known as The Drug Enforcement Administration ("DEA"), to all practitioners who prescribe and/or dispense drugs and to pharmacists who dispense drugs.

tion was filled, (i) the Schedule II substance NDC number,* (j) the pharmacy BNDD number and (k) the signature of the dispenser. A sample copy of such a form is annexed hereto marked "Exhibit D".

B. *Organization of Bureaus of Department of Health Which Process or Use The Forms*

5. Dr. Arthur G. Baker, Associate Commissioner of Health for Community Health Services, is charged with overall responsibility for the triplicate prescription program. Two bureaus under his jurisdiction have responsibilities relating to the triplicate prescriptions—the Bureau of Narcotic Control ("BNC") and the Bureau of Controlled Substances, Licensing and Evaluation ("BCSLE"). The BNC, under its director, John J. Bellizzi, is responsible for conducting investigations concerning alleged violations of the Public Health Law relating to controlled substances. There are 24 narcotic investigators in BNC, distributed throughout the state as follows: 2 each in Buffalo, Rochester, Syracuse, White Plains and Albany, and the remaining 14 in New York City. The BCSLE, under its director, Joseph L. Cannizzaro, is responsible for processing of the prescriptions and security and retention of the prescriptions. BCSLE was formed after enactment of, and for the purpose of implementing, the triplicate prescription legislation. Twenty-four of its employees are principally concerned with such implementation. In addition, the Office of Electronic Data Processing ("OEDP"), a unit which is part of the Department of Health but not under Dr. Baker's jurisdiction,* participates in the processing of the prescription blanks by transferring the in-

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*"NDC" refers to National Drug Code.

*At the trial, further evidence on this subject will be offered by defendant.

formation from the prescription blanks to discs to tapes which can be "read" by the computer. In April 1973, the director of OEDP was Harold Gottheim. The director of OEDP since March 1974 has been Joseph Bonacci. Implementation of the triplicate prescription law necessitated the hiring of 14 additional key punch operators and one additional computer operator.

C. *Processing of the "Cashed" Prescription Blanks in Albany*

6. In Albany, the prescriptions are received in the mail room of BCSLE, at 845 Central Avenue. They are taken unopened to a receiving room where they are opened, coded, put into batches of 100 each and logged by approximately nine clerks. Since April 1, 1973, the effective date of the law, prescription forms have been received at the rate of approximately 25,000 per week or over 100,000 per month.

7. The batches are then taken into a "processing room" which is part of the OEDP, where the information on the triplicate forms is keypunched onto discs and subsequently the information on the discs is transferred to magnetic tapes.

8. The prescription forms which have not yet been processed are stored overnight in a locked cabinet. Those which have already been processed are stored in a locked vault. The magnetic tapes containing triplicate prescription information are kept in a locked cabinet in an area of the processing room separate and apart from all other tapes and discs.

D. *Development of a Format for Presentation of the Information Contained On the Triplicate Prescription Forms Filed in Albany*

9. Prior to the enactment of the statute on June 8, 1972, no one from the Department of Health was asked to testify about the need for identifying information as to patients using Schedule II drugs. Although Bellizzi has been head of enforcement in New York since 1958, he was not consulted by the legislature about the need for triplicate prescriptions until after the statute was enacted.

10. After June 8, 1972, the Department of Health began to consider how the triplicate prescription information could be used. Bellizzi was sent to California and Illinois, two states which had triplicate prescription statutes, and found that the two principal areas of benefit were in deterring forgeries and over-prescriptions of the drugs. Thereafter, no memorandum was prepared by the Department of Health setting forth the questions to be answered by the system until memoranda dated June 20, 1973, October 11, 1973 and October 23, 1973, all of which were prepared more than one year after the statute had been enacted. However, from April 1973 to September 1973, the Department of Health was restrained from processing the prescription forms by this Court, the United States Court of Appeals for the Second Circuit and the United States District Court for the Western District of New York. The June 20, 1973 memorandum, prepared by Mr. Bellizzi for Commissioner Whelan, did not mention the possibility of apprehending patients who go from doctor to doctor to obtain excessive amounts of Schedule II drugs as a potential benefit of the system. The October 11, 1973 memorandum also did not mention the problem. The October 23, 1973 memorandum was divided into 18 questions to be answered monthly on a first priority basis, 25 additional questions

to be answered monthly, 3 questions to be answered quarterly, one question to be answered semi-annually and 5 questions to be answered on an "on request basis". None of the 15 questions to be answered on a "first priority basis" contained any request for information as to patients who go from doctor to doctor in order to obtain excessive amounts of Schedule II drugs.

11. Thereafter, on November 29, 1973, three schedules were prepared showing the information to be derived from the system (copies thereof are annexed hereto marked "Exhibit E", "Exhibit F" and "Exhibit G") and, in early December 1973, a further memorandum was prepared describing the format of the information to be obtained in greater detail. (A copy thereof is annexed and marked "Exhibit H"). According to Dr. Baker, the four basic purposes of the system were as follows:

(a) To facilitate study of the practicing habits of those practitioners who use an unusually large number of prescriptions. Dr. Baker plans to obtain a list of such physicians and then a printout of the types of drugs prescribed or dispensed by such physicians and to refer that information to the Bureau of Narcotic Control which will pursue an audit of such physician's practices to ascertain whether such usage was proper.

(b) To obtain the information contained on Exhibits E, F, and G.

(c) To obtain information on selected drugs that may present a problem of abuse. Dr. Baker plans to follow the same process of investigating physicians who prescribe these drugs as is described in subparagraph 11(a) above.

(d) To ascertain instances in which patients appear to be obtaining more than a 30-day supply of a controlled substance, possibly by obtaining prescriptions from more than one physician.

12. The only information from the computer which Dr. Baker contemplates would contain the names of any patients is a print-out of patients who have obtained more than a 30-day supply of a Schedule II drug in a 30-day period. The only reason given by Dr. Baker for the above print-out is that it will assist in the identification and investigation of persons who, using the same name, go from doctor to doctor to obtain an illicit supply of Schedule II drugs. The number of case reports of such violations was as follows from January 1, 1969 to May 12, 1974:

1974 — 1 case

1973 — None

1972 — None

1971 — 1 case

1970 — 1 case

—

1969 — 1 case

E. *Print-outs Now Being Produced By the State's System*

13. As presently in effect, the following print-outs are produced by the state's system:

(a) "Practitioner RX Transaction Record Edit Error Listing." This print-out sets forth errors which occurred in the process of transferring the information from the prescription form as filed in Albany to the computer tape on which the information is stored or to deficiencies contained on the prescription.

(b) "Schedule II substances dispensed and processed in month. . . ."

(c) "All prescriptions processed in month. . . ." This shows, *inter alia*:

(i) The number of prescriptions filled and the average number of prescriptions per practitioner;

(ii) The number of prescriptions dispensed by practitioners;

(iii) The number of prescriptions dispensed by pharmacies.

(d) "Report of duplicate prescriptions processed in month. . . ." This shows when two prescriptions with the same number were filled. While the purpose of this print-out was to detect possible forgeries or counterfeits, all duplications uncovered have resulted from errors in processing.

(e) "Unmatched BNDD numbers." This print-out was designed to show prescriptions filled where the practitioner's BNDD number listed on the prescription did not match the BNDD number shown on Department of Health records for the practitioner. It too was designed to protect against possible forgeries, but, in April 1974, "in the process of being modified."•

(f) "Patients with prescription total in excess of 30-day supply processed in month. . . ." This is the print-out designed to ascertain the identity of patients who go to more than one doctor to obtain an excess of a 30-day supply of Schedule II drugs within a 30-day period. Originally, this print-out did not contain patients' names, but, in April 1974, it was being altered so that patients' names would be included and

• Mr. Cannizzaro will testify, on behalf of defendant, that this print-out is no longer being used.

it is presently being printed out with the patients' names.

(g) "Alphabetical listing of practitioner master file." This print-out sets forth all practitioners that order triplicate prescription blanks and is used to facilitate the ordering and re-ordering of prescription blanks by the Department of Health and to check the practitioner's BNDD number.

(h) "New York State Department of Health list of licensed physicians." This print-out is used as a check in the ordering process.

(i) "Master mailing file." This print-out sets forth all physicians to whom triplicate prescriptions have been mailed in a month and is used for the same purpose as the print-outs described in subparagraphs "g" and "h" above.

14. All of the above print-outs are issued monthly except the "Practitioner RX Transaction Edit Error Listing" which is issued daily. The only person authorized to receive the print-outs from OEDP is Mr. Cannizzaro. Mr. Cannizzaro and Dr. Baker decide who should receive any of the information contained in the print-outs.

F. *Use of Patients' Names By the System*

15. The only print-out which contains patients' names is that described in paragraph 13(f) above. That print-out has been received by Mr. Cannizzaro since October 1973. Up to February 9, 1974, Cannizzaro had not given a single patient's name to BNC. By June 1974, BCSLE, under Mr. Cannizzaro, uncovered only two patients by use of the computer, who had apparently gone from doctor to doctor to obtain excessive amounts of drugs within a 30-day period. Mr. Cannizzaro wrote two memoranda, referring the names

of such patients to BNC. The two referrals were investigated by BNC. One investigation disclosed a *bona fide* patient relationship. The other is still pending.

16. In addition, BCSLE received approximately five or six requests from the BNC relating to particular patients. The substance of these requests was that an investigator had been informed that a patient was going to one or two physicians in a certain area and he wanted to obtain a listing of all prescriptions received by such patients. However, the computer did not have the capability to give the information requested. It now has the capability. At no time up to April 24, 1974 had BCSLE received a request for information in response to which it gave the identity of a patient to BNC. Since the triplicate prescription information has been on file in Albany and up to April 24, 1974, BNC had received no information whatever from BCSLE in response to any request made by Mr. Bellizzi, through whom all such requests are made and, in Mr. Bellizzi's opinion, stated on May 21, 1974, the computerized information has been of no assistance to BNC.

G. *Access to Information On the Computer*

17. The triplicate prescriptions are presently being processed on a Burroughs 3500 computer, which will soon be replaced by a Burroughs 6700 computer. There are several remote terminals that have access to the computer, but not to the triplicate prescription data. However, adjustments to the computer which would permit such access could be made.

18. In November 1974, at least 31 employees of the New York State Department of Health had access to all computerized information with respect to patients: two employees in the Office of the Commissioner for Community

Health Services, one employee in the Office of Management Analysis, four employees in the OEDP and 24 employees in the BCSLE.

19. No patient has ever been permitted to ascertain what information about him is held in the Department of Health or whether any such information is accurate and no verified request for such information has been received by defendant.

II. *Issues*

A. The parties agree that the issues to be tried are as follows:

(1) Does the centralized filing and computerization of the information, including the patients' names contained on official New York State prescription blanks with respect to Schedule II substances, invade the constitutional right of privacy of patients?

(2) Does such centralized filing and computerization invade the patient's constitutional right to receive medical care in accordance with his licensed physician's best medical judgment?

(3) Does centralized filing and computerization of official New York State prescription blanks violate the constitutional right of doctors to administer medical care in accordance with their best medical judgment?

(4) Is there a compelling state of interest for such centralized filing and computerization?

(5) Are the steps taken by the State adequate to protect patients from the risk of malicious or careless disclosure of such centralized and computerized information?

B. In addition, defendant believes that the following is an issue:

> Should the constitutionality of the provisions of the New York Public Health Law requiring the centralized filing of official New York State prescription blanks with respect to the prescribing and dispensing of Schedule II substances be determined by the application of the "compelling state interest" test or of the "rational basis" test?

III. *Exhibits*

Schedules of the exhibits which each party intends to offer at trial and of objections thereto are annexed hereto. Should any party desire to offer additional exhibits, prompt notice of that fact shall be given to the other party and to the Court in writing.

IV. *Witnesses*

The parties agree that the witnesses whom each party intends to call are as follows:

A. *Plaintiffs' expert witnesses:*

(1) Joseph Wasserman.

Summary of qualifications. Mr. Wasserman is president of Computer Audit Systems Inc., a firm which specializes in providing auditors and accountants with computer audit software, electronic data process training courses, consulting services, and computer security reviews of data centers. He has worked directly in the field of computer auditing for 12 years, holding management positions in the Bell Telephone System prior to assuming his present responsibility.

Mr. Wasserman has published numerous articles for the audit profession, including (i) "Control in an EDP Environment," September/October 1970 Internal Auditor; (ii) "Plugging the Leaks in the Computer System," September/October 1969 Harvard Business Review; (iii) "The Vanishing Trail," July/August 1968 Bell Telephone Magazine; (iv) "Internal Auditors, Where Do You Get Them—How Do You Train Them," Proceedings of the 25th International Conference of the Institute of the Internal Auditors, 1966.

Area of testimony. Mr. Wasserman will present an analysis showing that as of January 23, 1974, a date when he visited the computer facility used to process the triplicate prescription forms, (a) the physical security, procedural security and data security of said facility and the computer system located there were inadequate; and (b) computerizing the patients' name is not reasonably calculated to achieve the stated purposes of the system.

(2) Jerry M. Rosenberg, Ph.D.

Summary of qualifications. Dr. Rosenberg is Chairman and Professor of the Department of Management at Polytechnic Institute of New York, has also taught at Cornell University and Columbia University and was a visiting professor at the University of British Columbia and the Israel Institute of Productivity. Dr. Rosenberg is the author of various books and articles, including, "The Death of Privacy" (1969); "The Computer Profits" (1969); "The Need For A Renewed Conception of Technical Education" (1967); and "Automation, Manpower and Education" (1966). In addition, Dr. Rosenberg has testified at the hearings on "Federal Data Banks, Computers and the Bill of Rights" held by the United States Senate Sub-Committee on Constitutional Rights of the Committee on the Judiciary.

Pre-Trial Order on Consent.

Area of testimony. Dr. Rosenberg will testify as to the psychological damage to the individual from having his behavior perceived and recorded by a central agency.

B. *Plaintiffs' other witnesses:*

(1) Robert Roe.

(2) Mary Doe.

(3) Michael Moe.

(4) Jane Roe.

(5) Matthew Brody, M.D.

(6) Israel L. Schmierer, M.D.

C. *Intervenors' witnesses:*

(1) Martha Patient.

(2) Gerald Lustig, M.D.

(3) David Hain, M.D.

D. *Defendant's witnesses:*

(1) Joseph L. Cannizzaro.

(2) Joseph Bonacci.

Should any party hereafter desire to call any additional witnesses, prompt notice of their intention shall be given to the other party and to the Court. No witnesses may be called at trial unless so identified.

V. *Plaintiffs' Contentions*

Plaintiffs contend as follows:

A. The State can show no need nor compelling state interest which would warrant the centralized filing

Pre-Trial Order on Consent.

and computerization of the information, including the patients' names, contained on official New York State prescription blanks with respect to Schedule II substances.

B. Such centralized filing and computerization invades the constitutional right of privacy of patients.

C. Such centralized filing and computerization does not achieve any legitimate purpose of the State.

D. The means used by the State are unreasonably broad to achieve the designated purposes and thus constitute an invasion of the patients' constitutional right of privacy.

E. Such centralized filing and computerization invades the patient's constitutional right to receive medical care in accordance with his licensed physician's best medical judgment.

F. Centralized filing and computerization of official New York State prescription blanks violate the constitutional right of doctors to administer medical care in accordance with their best medical judgment.

G. The steps taken by the State are not adquate to protect patients from the risk of malicious or careless disclosure of such centralized and computerized information.

* * *

The trial herein shall be conducted in accordance with this Pre-Trial Order on Consent.

Dated: New York, New York, November , 1974.

U.S.D.J.

Pre-Trial Order on Consent.

CONSENTED TO:

SHEA GOULD CLIMENKO & KRAMER

By MICHAEL LESCH
A Member of the Firm

Attorneys for Plaintiffs

CONSENTED TO:

NORWICK RAGGIO & JAFFE

By MILES JAFFE
A Member of the Firm
Attorneys for Intervenors

CONSENTED TO:

LOUIS LEFKOWITZ

By .....
Assistant Attorney General
of the State of New York
Attorney for Defendant

Exhibit B, What You Should Know About Triplicate Prescriptions.

STATE OF NEW YORK
DEPARTMENT OF HEALTH

EXECUTIVE DIVISION
84 HOLLAND AVENUE
ALBANY, N. Y. 12208

November 28, 1973

Dear Doctor:

Recent actions by Federal courts in New York City and Rochester have resulted in a lifting of restrictions on the State Health Department with regard to the processing of triplicate prescription forms. In other words, the New York State Controlled Substances Act, which took effect April 1, 1973, including the processing of triplicate prescription forms, is in full force and effect.

As a result, the State Department of Health is analyzing information obtained from the triplicate prescriptions as they are filed with the Department. Summaries of this information will be published periodically in professional journals.

I am enclosing a copy of "What You Should Know About Triplicate Prescriptions," which I am sure you will find helpful.

Sincerely,

HOLLIS S. INGRAHAM, M.D.
Hollis S. Ingraham, M.D.
Commissioner of Health

Exhibit B, What You Should Know About Triplicate Prescriptions.

What You Should Know About Triplicate Prescriptions

Triplicate Prescriptions

1. Use for *Schedule II Drugs Only*
2. No more than a 30-day supply (when used as directed) may be prescribed at one time.
3. Triplicate Prescriptions are *not* refillable.

How to Obtain Triplicate Prescriptions

Triplicate prescription forms may be ordered, at a cost of $10.00 per 100, from the Bureau of Narcotic Control, 845 Central Avenue, Albany, New York, 12206. To reorder, complete the reorder form and return it to the Bureau of Narcotic Control.

How to Complete Triplicate Prescription Forms

1. Use ink, indelible pencil or typewriter. (*Please Be Legible*)
2. Be sure to complete *all* information requested on the form.
3. Give the original and one copy to the patient and instruct him to take *both* to his pharmacy when having the prescription filled. *The prescription must be presented to the pharmacy within 30 days of the date the prescription was signed. It cannot be filled after the 30 day period.*
4. Retain your copy in your office for 5 years and have it available for inspection.

Dispensing Schedule II Substances by Practitioners

If a practitioner dispenses Schedule II Substances from his office stock, he must:

Exhibit B, What You Should Know About Triplicate Prescriptions.

1. Complete the triplicate prescription form as indicated, including the dispenser's portion, i.e., National Drug Code Number and Dispenser's Signature.
2. Forward the original and one copy to the New York State Bureau of Narcotic Control, 845 Central Avenue, Albany, New York, 12206 *not later than the 15th of the month following the month in which the drug was dispensed.* Retain the practitioner's copy for 5 years.
3. Dispense the drug in a suitable and durable container with a firmly affixed Orange Label containing the following information:
   a. The legend prominently marked or printed in bold face or upper case lettering: "Controlled Substance, Dangerous Unless Used as Directed."
   b. Name of the drug or its National Drug Code Number
   c. Name and address of patient
   d. Name, address and telephone number of the dispensing practitioner
   e. Specify directions for use
   f. Date of filling

Emergency Oral Rxs for Schedule II Drugs

In an emergency a practitioner may *authorize an emergency oral* prescription for a Schedule II drug. No more than a 5-day supply may be prescribed orally. Within 72 hours after authorizing an emergency oral prescription, the prescriber must deliver the original and one copy of the triplicate prescription form to the dispensing pharmacist. The words "*Authorized for Emergency Dispensing*" shall be written or typed across the face of the prescription. If the pharmacist fails to receive such prescription, he must notify the State Health Department in writing within 7 days after dispensing the drug.

Exhibit B, What You Should Know About Triplicate Prescriptions.

GROUP PRACTICES

Each physician in a group practice who prescribes or dispenses Schedule II drugs must use his own triplicate prescription forms. Triplicate prescriptions are not transferable and may be used only by the practitioner to whom they were issued.

NEW YORK STATE DEPARTMENT OF HEALTH

TWO OR MORE OFFICES?

If a practitioner has two or more offices at different locations where Schedule II drugs are maintained or dispensed, separate books of triplicate prescription forms must be obtained for each location where Schedule II drugs are dispensed.

EXAMPLES OF SOME FREQUENTLY PRESCRIBED SCHEDULE II DRUGS REQUIRING THE USE OF TRIPLICATE PRESCRIPTION FORMS:

Analgesics	*Anoretics*	*Others*
Codeine	Benzedrine	Cocaine
DEMEROL*	BIPHETAMINE*	INNOVAR*
DILAUDID*	BIPHETAMINE T*	OPTIMAL*
DOLOPHINE*	DESOXYN*	PAREST*
LEVO-DROMORAIN*	DEXAMYL*	QUAALUDE*
LERITINE*	DEXEDRINE*	RITALIN*
MEPERGAN*	Dextro-Amphetamine	SOMNAFAC*
Morphine	ESKATROL*	SOPOR*
NUMORPHAIN*	METHEDRINE*	
Opium	OBETROL*	
PANTOPON*	PRELUDIN*	
PERCOBARB*		
PERCODAN*		

* Brand Names in Capitals

Exhibit B, What You Should Know About Triplicate Prescriptions.

For further information, call the nearest office of the Bureau of Narcotic Control:

NYS Department of Health
Taxation & Finance Bldg. No. 9
State Campus, Albany, NY 12226
Telephone 457-5150

NYS Department of Health
1222 Commerce Building
119 East Main Street
Rochester, New York 14604
Telephone 546-6556

NYS Department of Health
584 Delaware Avenue
Buffalo, New York 14202
Telephone 842-5038

NYS Department of Health
677 South Salina Street
Syracuse, New York 13202
Telephone 473-8388

NYS Department of Health
Two World Trade Center
49th Floor
New York, New York 10047
Telephone 488-3933

NYS Department of Health
901 North Broadway
White Plains, New York 10603
Telephone 761-7900

IF TRIPLICATE PRESCRIPTION FORMS ARE LOST OR STOLEN, NOTIFY THE BUREAU OF NARCOTIC CONTROL IMMEDIATELY.

jbesb

Transcript of Proceedings (12/2/74).

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

- x

RICHARD ROE, AN INFANT BY ROBERT ROE, HIS PARENT; JOHN DOE, AN INFANT BY MARY DOE, HIS PARENT; JAMES MOE, AN INFANT BY MICHAEL MOE, HIS PARENT; JANE POE, MATTHEW T. BRODY, ISRAEL L. SCHMIERER, and EMPIRE STATE PHYSICIANS GUILD, INC.,

Plaintiffs, — 73 Civ. 1303 R.L.C.

vs. — 73 Civ. 1431 R.L.C.

HOLLIS S, INGRAHAM, as COMMISSIONER OF THE STATE OF NEW YORK HEALTH DEPARTMENT,

Defendart,

GEORGE PATIENT, MARTHA PATIENT, GERALD L. LUSTIG, and THE AMERICAN FEDERATION OF PHYSICIANS AND DENTISTS,

Intervenors,

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Before:

HON. WILFRED FEINBERG,

Court of Appeals Judge

HON. INZBER B. WYATT,
HON. ROBERT L. CARTER,

District Judges.

December 2, 1974
10:10 a.m.

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APPEARANCES:

SHEA, GOULD, CLIMENKO & KRAMER, ESQS.
Attorneys for Plaintiffs

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BY: MICHAEL FOGARTY, ESQ.
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Attorneys for Intervenors (co-plaintiffs)

BY: H. MILES JAFFE, ESQ.
RISA DICKSTEIN, ESQ., of Counsel

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JUDGE FEINBERG: Can we get the record at this point straightened out?

The intervenors are really co-plaintiffs; is that correct?

MR. JAFFE: Yes.

JUDGE WYATT: In a separate action?

MR. JAFFE: That's right.

JUDGE WYATT: Two separate actions for the same relief.

MR. JAFFE: We have been consolidated.

JUDGE WYATT: Not by order but by practice.

MR. JAFFE: I believe initially they were consolidated by order, going back to April of 1973, and then consolidated again in the Circuit Court, I believe, and I think we filed an order today consolidating for the purposes of trial, although I think that is redundant, frankly.

JUDGE FEINBERG: In any event, we will refer to your clients as plaintiffs, also. There are no more intervenors.

JUDGE WYATT: If you find any order of consolidation, I would be glad if you would bring it to our attention because a search of the docket entries by my staff has indicated that as far as the docket entries are

concerned, there has never been any order of consolidation.

MR. JAFFE: All right, your Honor. I will look for that.

JUDGE FEINBERG: Mr. Lesch?

MR. LESCH: Your Honor, we have throughout these proceedings referred to the plaintiffs by assumed names and with the Court's permission, we would like to continue to do so, even when they are sworn in.

If the Court wishes to have a list of the actual names of the plaintiffs, I have them here and we will give them to the Court.

JUDGE FEINBERG: Would you do that, please, and hand it up.

(Document handed to the Court.)

MR. GREENWALD: Of course I think the defendants are entitled to that list at this time.

MR. LESCH: Yes, they are, and I, unfortunately, only have one copy but I will advise the defendants of the actual names of the plaintiffs.

JUDGE WYATT: What about the plaintiffs in the other action?

MR. JAFFE: Your Honor, I did not make up a list but I have provided the names. We will provide the names to the Court.

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JUDGE FEINBERG: Thank you.

Mr. Lesch?

MR. LESCH: I call Mr. James Moe.

JUDGE FEINBERG: I am handing this list back to the clerk to give to you, Mr. Lesch.

J A M E S M O E, called as a witness by the plaintiff, being first duly sworn, testified as follows:

DIRECT EXAMINATION

BY MR. LESCH:

Q Mr. Moe, what is your profession?

A I am a lawyer.

Q How long have you been a lawyer?

A In New York State since 1961.

Q And were you admitted to the Bar prior to your admission in New York?

A I was admitted to the Bar of the State of Ohio in 1960.

Q And do you have any children?

A Yes.

Q How many?

A Two.

Q Do you have a son that suffers from a condition known as hyperkinesia?

A Yes.

Q How old is he, sir?

A Six and a half.

Q And when was his condition first diagnosed?

A Within the second six months of his life, sometime between achieving six months and a year.

Q Will you describe the condition of your son which is known as hyperkinesia?

A Well, as we saw it, it was principally uncontrolled motor activity. The child seemed not to be able to fully keep himself able to do as he wanted to do; inability to focus on anything for more than a few seconds at a time; some disorientation as he woke up in the middle of the night.

I think those were the principal symptoms.

Q And did you bring your son to a doctor when those conditions became evident to you?

A Yes. We had been talking to our pediatrician who then referred us to a child psychiatrist.

Q And did that doctor prescribe a drug?

A Eventually, yes.

Q And what was the name of that drug?

A Well, the ultimate drug that was used regularly has the trade name of Ritalin.

Q And prior to the time that that drug was used by your son, did you have conversations with physicians concerning the necessity of the use of that drug?

A Yes, I surely did.

Q Without going into individual conversations, can you give us the substance of those conversations?

A Yes. When it was suggested that an amphetamine or amphetamine-like drug be used, both my wife and I were concerned and expressed that concern and we had conversations with Dr. Porter, the child psychiatrist to whom we were referred; Dr. Alfred Fisher, the child's pediatrician; and several physicians of my personal acquaintance, all of which were trying to find out whether there was an alternative, what we might read to assist us in deciding whether it was suitable, and so forth.

Q And was there a unanimous opinion of those doctors?

A There was.

Q What was that opinion, sir?

A That the child would have to take something like Ritalin in order for him to have any hope of having a normal childhood and learning.

Q Did there come a time when you first learned about what I will refer to as the triplicate prescription

requirement, namely, the requirement that one copy of the prescription containing your son's name be filed in Albany?

A Yes.

Q When was that, sir?

A I don't recall the date but it was sometime after the -- shortly after the bill was enacted and before it took effect.

Q And with whom was that conversation?

A Dr. Robert Porter.

Q What did Dr. Porter say on that occasion?

A He told me of the new legislation and explained to me that he would have to henceforth, on a given date that was shortly coming, begin to file these forms with the State.

I protested strongly. I was very upset, which I expressed to him, and I told him that I had trouble accepting that the legislation could be as he described it, given the fact that the child was getting a normal treatment for a known medical disorder and this was the customary treatment for it.

I had difficulty -- and giving his age, four at the time, something like that, I had trouble accepting that the legislation really could be as he said it was and subsequently, I had a second conversation with him on the

same subject after I examined the legislation in which we agreed that the legislation did, indeed, seem to require it and which he and I discussed whether there was any alternative to keeping the child on an amphetamine since the legislation was the way it was.

Q And what was the result of that conversation?

A Well, he stated that he knew of no new choice of possible treatment for my boy and we had both agreed previously that that seemed to be the only thing we could do, so we agreed that we were, in essence, stuck.

Q And has your son received Ritalin since the effective date of the act, which was April 1, 1973?

A Yes, he has.

Q Do you continue to object to the requirement that a copy of the prescription with his name be filed in Albany?

A Yes, I surely do.

JUDGE WYATT: Are they actually filing the prescriptions?

THE WITNESS: I don't know, your Honor. I assume so.

MR. LESCH: No further questions.

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CROSS-EXAMINATION

BY MR. FOGARTY:

Q Mr. Moe, how did you first learn about the statute?

A From Dr. Robert Porter.

Q Exactly what did he tell you about it?

A He told me that henceforth he would have to file a copy of the prescription form or a similar form with the State Government, showing precisely the amounts prescribed, the drug prescribed, the name of the person it was prescribed for and the address.

Q Are you familiar with prescription blanks generally?

A Yes.

Q What do they contain?

A Well, I believe the name of the patient, the address and, of course, the drug they prescribe.

Q What happens to those?

A Well, they are given to a pharmacist, I guess.

Q You don't know?

A I believe they are given to the pharmacist.

Q What happens to them then?

A I don't know. I believe the law requires the pharmacist to keep it for a certain period of time.

Q Didn't that disturb you, that your child's name was on that prescription blank?

A No.

Q Could you tell us what the difference is between that blank and this one?

A Well, it is hard to say what the operation of my mind was at the time that one upset me and not the other, but sitting here today, it seemed to me the major difference is the lack of organization that -- and the lack of system where, with whatever pharmacist you happen to turn it in to, kept for Lord knows how long and -- as opposed to going on to a central computer kept by a government.

Q What is your objection to the central computer run by a government?

A Well, the system of it. The ease of retrieval of the information and that it is kept by a government. I don't believe they have any right, the Government has any right to that information.

Q Are you aware that under the old prescription system, the Government had the right to the information?

A Well, I am aware of it only in the sense that I suppose they could demand any given pharmacists --

Q I don't want to know what you suppose.

A Then I shouldn't answer at all. No, I don't know.

Q You don't know?

A No; not familiar with it.

Q Who alerted you to the great danger with the change in method?

A Well, I described the conversation. I am not sure I understand the question.

Q How much detail did the doctor go into with you when he told you about this prescription law?

A Simply what I have stated -- that he would have to file a copy of every prescription or the same information with the State Government.

JUDGE WYATT: Tell me, did the doctor himself deliver to you the amphetamine?

THE WITNESS: Initially, yes; subsequently, no. After about six months we started getting it at a pharmacy.

JUDGE WYATT: When you got it at a pharmacy, I take it the doctor gave you two copies of the prescription.

THE WITNESS: I don't believe so. I think just one.

JUDGE WYATT: And you gave that to the pharmacist?

THE WITNESS: That's correct.

JUDGE WYATT: And your understanding was that the

doctor himself was sending the copy to the State?

THE WITNESS: After the new system. I believe so, yes.

JUDGE WYATT: I think technically the law is that it is the pharmacist who has to send the copy. I don't think it makes any difference.

MR. LESCH: It doesn't make any difference, but your Honor is correct, yes.

MR. FOGARTY: Except in the situation where the doctor dispenses it himself.

JUDGE WYATT: Yes, and the witness says there came a time when the doctor did not himself deliver the amphetamine.

BY MR. FOGARTY:

Q What happens to the information that goes to Albany?

A If I understand it, it is put on a computer, in a computer memory bank.

Q What happens then?

A I don't know what is done with it today.

Q Well, you have expressed a concern, an alleged invasion of privacy?

A That's correct.

Q Now, there must be a reason for that. The

computer in and of itself is a machine, an inanimate object.

What happens to the information that goes into there?

A When you say what happens to it, I don't know what actually happens to it.

If you are asking me what my fear is, I would be pleased to respond to that.

JUDGE CARTER: Isn't that really what the question is. Why should he be required to know what happens to it? It is a question of what his concerns are; isn't that what the issue is here?

MR. FOGARTY: Well, his concerns, yes, and the basis for them.

JUDGE CARTER: Well, the basis for them is the basis in his mind of what he fears.

MR. FOGARTY: That is what I am getting at.

JUDGE FEINBERG: What is it you are concerned about?

THE WITNESS: Well, by the time my boy is an active citizen, there will be a long file on him in a narcotics or dangerous drug context, in which somebody can get a print-out and use it, once they have it, for whatever they use it for.

I have visions -- however, perhaps they are

merely my own visions -- but I have visions of the boy getting into, say, some minor scrap with the law and a probation officer, or something of the sort, having a long history of drug use and given the emotional attitude towards drugs and the fact that the probation officer or, indeed, a judge wouldn't have done the research that I did or that the doctor, there may be a feeling that they have on their hands a different sort of person than they do.

There are so many emotional aspects to a long history of something called a dangerous drug and this is my concern; the fact that it is in one place under a name, can be retrieved presumably by using that person's name.

These are the things that -- the kind of things that bother me. It is hard to articulate precisely how I see it being a problem for the boy but, basically, I can't tell and I have had enough experience with the misuse of information by governments and others that I worry very much about the availability of this information in such a systematic way.

JUDGE WYATT: But this information would indicate that in every case your child received this drug on the prescription of the physician licensed to practice in New York.

Wouldn't that make a difference?

THE WITNESS: Well, firstly, your Honor, I don't know the form in which -- every form in which the computer will permit retrieval. I don't know whether it will give you everything in the file every time you press a button or whether or not it can be programmed or reprogrammed to give you selective information.

JUDGE CARTER: But suppose it does?

THE WITNESS: Gave the information that Judge Wyatt referred to?

Certainly that is better and less concerning than if it didn't but, no, the history would still be the same; there would still be the possibility of the governmental agent believing that the child had a long history of drugs, so long that it might be -- lead to a different view of the child than should be taken.

It is very difficult. I'm sorry; it is difficult to articulate exactly why that would concern me but it does.

BY MR. FOGARTY:

Q Let's assume, since you are an attorney and you know some of the procedures that are involved, that your son gets into a slight scrape with the law.

Don't you think that in a probation report, they would go see a physician and check the local drug stores and get the same information that you don't want disclosed?

A That would certainly be different than my understanding of the trouble taken.

Q In other words, you are presuming the worst of the State Department of Health and the best of everybody else.

MR. LESCH: Objection.

JUDGE FEINBERG: Sustained.

Q Are you aware of the provisions of Section 3371 of the law?

A Not by number.

JUDGE FEINBERG: What provision was that, Mr. Fogarty?

MR. FOGARTY: 3371, your Honor, confidentiality.

Q Do you know what confidentiality is, Mr. Moe?

A I know what confidentiality is.

Q Have you read this section?

A Yes, I have.

Q Do you know what it means?

A I know what it says.

Q I think we presume it means what it says, don't we?

A I have no reason not to.

Q Did that allay any of your fears?

A No.

Q Why not?

A Well, firstly, it is part of legislation. It was enacted by a group of legislators and can be amended by them.

Secondly, you know, that kind of thing can be abused and it can be misused. It can be procured for one reason and used for another.

The fact that a statute on the books says that information is confidential does not reassure me that in fact it won't be used.

Q In other words, you have no confidence in the law?

MR. LESCH: I object.

JUDGE FEINBERG: Sustained.

Q Or public officials.

If I were to state and we were to show in this case that the information in that computer is used for print-outs of about a half a dozen different types and that only one of those computer print-outs gives the name of the patient, would that allay your fears in any way?

A Well, not offhand. I don't fully understand what you are saying.

Q Well, you are talking about pushing buttons and a computer and getting print-outs and I am telling you that there are about a half a dozen print-outs coming out of the machine and that only one of them contains the name of the

patient.

A No.

Q This is going to be proven in this case.

A And what is your question?

Q Does that allay any of your fears?

A No.

Q No? Well, suppose I were to tell you and we were to produce evidence at this trial that the only time that a patient's name is printed out of that computer is when he receives in excess of a thirty days' supply within that period, would that allay any of your fears?

A No.

Q Why not?

A Well, I assume that someone has made the decision that the print-outs are to be taken out that way and I assume that decision is subject to change.

Q Well, suppose I were to tell you that that decision is based on determining violations of the drug laws, since it is against the law for a physician to prescribe more than thirty days' supply of a Schedule 2 drug,except in one instance that I will relate to you in a moment.

A What is your question?

Q The question is, would that allay any of your

fears? I am telling you why the print-out is made.

A No, it would not allay my fears.

Q Do the drug laws at all give you any cause for concern?

A Do the drug laws?

Q Violations of them.

A Certainly, as a citizen and a lawyer.

Q You are concerned about the welfare of your children which is why you are here.

Are you concerned at all that your son even for a limited time has taken what the legislature has described as a dangerous drug?

A Well, I was concerned about it prior to his having taken it. As I say, we did a lot of reading, talked to a great many people and were persuaded that it was not a matter of concern.

Q Do you know what the nature of the drugs are that are in Schedule 2?

A I believe it is a mixture of opium-related drugs and amphetamine-related drugs.

Q Have you ever heard them described as having a high incidence for abuse?

A Well, I don't know that I have but I can see that that would be a possible description.

Q Don't you think this concern for your child might extend to what he is taking?

A You mean taking of Ritalin?

Q The amount of it he takes.

JUDGE CARTER: What has that to do with the statute With the issue before us?

MR. FOGARTY: Your Honor, this prescription goes to Albany and the only print-out where it comes out with a name on it is where an excessive amount has been prescribed.

Now, this can occur through accident but the State Department of Health becomes aware of it through a print-out.

They don't go back to this witness. They go to the pharmacist, to find out if a mistake was made, and this is the point of my questioning.

The concern here for the child seems to be extremely limited and there don't seem to be any factors which will change his mind.

MR. JAFFE: I object to that. That is not what he testified to.

JUDGE FEINBERG: Sustained.

THE WITNESS: I'm sorry. Are you asking me --

JUDGE FEINBERG: There is no question before you.

MR. FOGARTY: I was replying to Judge Carter; I was

not asking you anything.

Q Are there any alternative drugs available?

A The only known alternative drugs for extreme hyperkinesia are also amphetamines, benzedrine, dexadrine.

Q How long is your son going to be on the drug?

JUDGE WYATT: Isn't he following the advice of a licensed physician? Is it his opinion that is relevant? He is simply doing what his doctor told him to do, as I understand it.

JUDGE CARTER: What difference does it make how long he is going to be on the drug?

MR. FOGARTY: Because there is another section of the law that I think may allay some of his fears and I am trying to point out that he doesn't know what the law is. He has been told something by a physician and that's all he knows.

JUDGE CARTER: The issue as far as he is concerned is that he thinks that somebody, someplace in Albany, the Government is going to have a history of the fact that his son has been using this drug over a period of time and he is concerned that it may be put to adverse use; that is clearly what his concern is.

Whether it is valid or not is another question, and you don't make it valid by asking him questions.

MR. FOGARTY: Well, I think I do, your Honor. If I can --

JUDGE FEINBERG: What is it you wish to prove by this cross-examination?

MR. FOGARTY: Simply that he has got some notions put in his head strictly by a doctor that are not valid.

JUDGE FEINBERG: Why don't you go ahead and see if you can develop that, if you can.

BY MR. FOGARTY:

Q Could you answer my question as to how long? What is the prognosis for your son taking this drug?

A Sometime in his early teens it would, typically, be no longer necessary.

Q Do you have any idea of how long the information is retained by the Department of Health? The third copy of the prescription, I am talking about.

A No, I do not.

Q Would it surprise you to learn that it is five years?

MR. LESCH: I object to that.

JUDGE WYATT: Well, is that written in the statute?

MR. LESCH: There is an amendment to the statute that talks about the copy of the prescription form but

nothing about the computerized information, so I think the question is unintentionally misleading.

JUDGE FEINBERG: Were you referring to the prescription form?

MR. FOGARTY: I said the prescription form and I believe it calls for the expunging of the records.

JUDGE FEINBERG: You can bring that out on redirect if you wish to.

There is a requirement for keeping it five years?

MR. FOGARTY: Yes, your Honor. It was amended in 1974:

"The Department shall cause to be expunged or otherwise destroyed within five years from the receipt thereof any record of the name of the patient received by it pursuant to the filing of the --"

JUDGE FEINBERG: Are you suggesting that that also refers to the information on the computer tapes?

MR. FOGARTY: I am suggesting that it says "any record."

JUDGE FEINBERG: Can't you answer that question?

MR. FOGARTY: I say yes, emphatically. I think the language is very clear.

Q Were you aware, sir, that the records would not be kept beyond five years?

A I was aware of it. I was not as --

MR. JAFFE: Objection, your Honor. The law is brand new --

JUDGE FEINBERG: Gentlemen, this is a case being tried before judges and not before a jury. I think we will get along much better if you each let counsel explore whatever they have to explore.

If you think it is going on too long, object. If you think something is completely outrageous under the rules of evidence, object, but let's not waste time on arguing legal issues because that is what we have been talking about the last few minutes.

MR. JAFFE: I am pointing out that at the time the witness' child took this drug, there was no five-year limit.

A I did not recall that, if I knew it.

Q Would that allay your fears in any way?

A It limits them to a five-year period.

Q You are aware of what the prescription looks like?

A I've handled them many times. I have no specific recollection of just how the form looks.

Q I would like to show you a Xerox copy of it and ask you if that is your recollection of it (handing).

A Yes, I've seen this.

Q Is there anything on that form that isn't on the ordinary prescription blank?

A Well, a great deal but --

Q For instance?

A Well, with reference to law, Mr. Fogarty, there is a lot of reference to Schedule 2 substance and things of that sort but if you mean --

JUDGE FEINBERG: Is that one of the exhibits in the pretrial order?

MR. FOGARTY: Yes. It is one of the exhibits in the original petition.

JUDGE FEINBERG: Is it Exhibit D?

MR. LESCH: Exhibit D.

JUDGE FEINBERG: Why don't you refer to Exhibit D, then, in your questions.

JUDGE WYATT: It is part of the pretrial order, is it not?

MR. LESCH: Yes, it is, your Honor.

A In terms of information about the patient, it appears to have the same information.

Q So that, in effect, there hasn't really been any change as to what information is made public there?

MR. LESCH: I object to all these questions on the grounds of relevance, your Honors.

JUDGE FEINBERG: Objection overruled.

A The change that I have addressed myself to relates to what is done with the information, not the form in which it is given to the pharmacist.

Q Would you agree with me, sir, that the same information is being made available to the State of New York, to the Department of Health?

A The information that is on here is --

Q Is the same as it was on the old prescription blank that they still use for other schedules.

A It may be. I don't know. You see, I don't know the procedures previously.

Q Your son was on this prescription before Schedule 2 went into effect, wasn't he?

A Yes.

Q You saw those prescription blanks, didn't you?

A Yes. The prescription blanks.

Q And you had them filled by the local pharmacist?

A Yes.

Q It is the same information, isn't it?

A Yes.

No, if you are asking me what my point was, my point is rather to do with the central system, the computerization of the information. Not the prescription

form.

MR. FOGARTY: No further questions.

MR. LESCH: I have no questions on redirect.

JUDGE FEINBERG: Thank you.

(Witness excused.)

J A N E P O E, called as a witness by the Plaintiffs, being first duly sworn, testified as follows:

DIRECT EXAMINATION

BY MR. LESCH:

Q Do you have a disease known as encephalitis?

A I had that years ago but I am all over it now. I sleep well now but not the way it was before.

Q And do you suffer from any other diseases now?

A Yes, I do.

Q What are they?

A My eyes go up. I keep on looking at the ceiling all the time.

Q And does your doctor prescribe any drug to you for that condition?

A Yes, he does.

Q Do you know what the name of that drug is?

A It starts with "T." I don't know how to pronounce it but I know it starts with a "T."

Q Who is your doctor?

A Dr. Matthew Brody.

Q Did Dr. Brody ever have a conversation with you about what is done with prescriptions for that drug?

A Yes, he did.

Q What did he say to you about that?

A I don't know.

Q Did he tell you anything about filing the prescriptions in Albany?

A Yes, he did.

Q Did he tell you that they went on a computer?

A Yes, he did.

Q And what did you say to Dr. Brody when he told you that?

A I don't know.

Q Did you tell him that you objected to it, that you didn't want your name on the computer?

A Yes, I did.

Q Why didn't you want your name on the computer?

A Because I am not a dope addict.

MR. LESCH: I have no further questions.

CROSS-EXAMINATION

BY MR. FOGARTY:

Q Mrs. Poe, did Dr. Brody tell you you were going to

be called a dope addict?

A No, he didn't.

Q He didn't tell you that?

A No.

Q Do you know whether that information in Albany says you are a dope addict or not?

A No.

MR. FOGARTY: No further questions.

MR. LESCH: I have no further questions.

MR. JAFFE: I have one question, if I may.

REDIRECT EXAMINATION

BY MR. JAFFE:

Q Your doctor did tell you, did he not, that you would be listed in Albany? Did he not tell you that?

A I don't remember if he told me or not.

Q He told you your name would be there as a user of drugs, did he not?

A Yes, I think he did.

(Witness excused.)

MR. LESCH: With the Courts' permission, may the plaintiff Patient elicit testimony from one of his witnesses?

JUDGE FEINBERG: Yes.

M A R T H A P A T I E N T, called as a witness by Co-Plaintiffs, being first duly sworn, testified as follows:

DIRECT EXAMINATION

BY MR. JAFFE:

Q What is your present occupation?

A I am a housewife.

Q And would you tell the Court your present state of health?

A Excellent.

Q Do you suffer from any medical condition for which you receive treatment?

A Yes. I have migraine headaches.

Q And what is the drug or drugs which you take for that condition?

A I take fiorinal, codeine and Cathedot.

Q And are you familiar with what has been called here the triple prescription requirement in New York?

A Yes, I am.

Q Do you know which of those drugs must be prescribed by triplicate?

A The fiorinal and codeine. I don't know about the fiorinal but it is one pill.

Q How long have you been taking this drug?

A Since 1967.

Q And did there come a time when you were informed that the codeine would have to be prescribed by a different system?

A Yes. My doctor in New York told me in the late spring of 1973, early summer, I am not sure which it was.

Q And what did he tell you at that time?

A He told me that the prescription that he was going to write would have to be filed in triplicate, himself keeping one copy, the pharmacist keeping another copy and that the pharmacist would then send the information about what I was taking to a central computer or agency in Albany where it would be computerized.

Q What was your reaction to that?

A I was very, very angry. Very angry. I work from time to time with people who had trouble with confidentiality and computers and I was very, very upset with it.

Q Did you continue to take the drug?

A Absolutely. Could not help taking it.

Q Did there come a time when you attempted to get off the drug?

A Yes. At the end of last summer, I seemed to have a space when I didn't have the migraines. I usually get

them once a month and I only take the pills once or maybe twice during that month but I didn't seem to have any for a couple of months and I tried to do without it. My prescription was out. I had just moved so I tried to do without it.

Q Why did you try to do without it?

A Well, I had been thinking a great deal about the fact that it would be very nice to not be on any drugs at all. Nobody likes to take them and, also, I thought that it might be very nice to have my name not appear in a computer in Albany.

Q What happened after you ceased taking that drug?

A I did okay for about three months and then last month, I woke up with a blinding headache and my husband had to remain home from work and I had to go to Albany -- to Newburg to the hospital.

Q You were hospitalized for that migraine?

A Yes.

Q And that --

Q There they gave me fiorinal and codeine, that if I had had at home I probably wouldn't have had to go to the hospital.

Q And you were not normally hospitalized for the migraine?

A Never. First time.

MR. JAFFE: I have no further questions.

JUDGE WYATT: Did you take these pills or these drugs which you referred to only on the advice of a physician?

THE WITNESS: Absolutely.

JUDGE WYATT: And he was your own physician?

THE WITNESS: Yes.

CROSS-EXAMINATION

BY MR. FOGARTY:

Q I believe you were sitting in the courtroom when the previous witness was on the stand, the gentleman, the first witness?

A Yes, sir.

Q Did you hear the areas which I explored with him?

A Yes, sir.

Q Do you have any comments to make with regard to them?

A No, sir, other than that I agree with some of the things that he touched upon.

Q Now you say that your concern was aroused because you knew people who had trouble with computer information?

A Yes, sir.

Q What kind of information was that?

A Well, they generally had to do with arrest records and that sort of thing. I worked as a social worker for a while and as a case aide in a hospital and I ran into people who had had problems.

Q These were police records you were talking about then?

A In some cases they were and other cases they were psychiatric records, medical records of one sort or another.

Q Well, I would suggest that the information could be gotten from your physician if it was necessary anyway, couldn't it?

A Under a different set of circumstances than simply a print-out.

Q What kind of print-out --

A Well, I assume that my records with my physician are confidential.

Q Are you aware of the confidentiality provision of this statute?

A I am, having heard in this court that they are there.

Q But up until you came in this court, you didn't know about that, did you?

A No, I didn't.

Q Your physician didn't bother to tell you that?

A No, sir.

MR. FOGARTY: Thank you. No further questions.

REDIRECT EXAMINATION

BY MR. JAFFE:

Q Are you aware of other confidentiality provisions with regard to arrest records and --

A Yes, I am.

Q And have you had any experience in which those statutory confidentiality records have been breached?

A Yes, I have.

MR. FOGARTY: Objection.

JUDGE FEINBERG: Overruled.

Q You are familiar with the breaching of those records?

A Yes, I am, sir.

Q You also are aware from the questioning that this is only a statutory provision which is subject to change?

A Yes, sir, I am.

MR. JAFFE: No further questions.

MR. LESCH: I have no question.

JUDGE FEINBERG: Thank you.

(Witness excused.)

MR. LESCH: I call Dr. Matthew Brody.

M A T T H E W B R O D Y, called as a witness by the Plaintiffs, being first duly sworn, testified as follows:

DIRECT EXAMINATION

BY MR. LESCH:

Q Doctor, what is your profession, sir?

A I am a physician.

Q And how long have you been a physician?

A I was licensed in 1935.

Q Do you specialize?

A In neurology and psychiatry.

Q How long have you specialized in that area of medicine?

A Since 1942.

JUDGE WYATT: What kind of psychiatry, Doctor?

THE WITNESS: I am a psychiatrist.

JUDGE WYATT: You said you specialized in some sort of psychiatry.

THE WITNESS: I have my Boards in both neurology and in psychiatry.

JUDGE WYATT: Neurology and psychiatry.

THE WITNESS: Yes. Primarily I am a psychiatrist.

Q And would you give us your educational background?

A Yes, sir. Graduate of Harvard, 1931; Downstate Medical Center, 1935; rotating internship at Kings County Hospital and was in residence there in neurology. After that I spent four and a half years full time at Brooklyn State Hospital and since 1942, I have been in private practice.

Shall I continue?

Q Yes. Will you continue with your professional background to date?

A I am presently chief at Brooklyn Jewish Hospital, consultant at Brooklyn State Hospital, consultant at Gracie Square Hospital.

I have my Boards both in neurology and psychiatry. I am an impartial examiner in psychiatry for the Workmen's Compensation Board. I am a member of any number of societies, Fellow of any number of professional societies.

Q Have you written papers in the area of neurology and psychiatry?

A About fifty papers.

Q Have you lectured on those subjects also?

A Yes, sir.

Q Are you familiar with the Empire State Physicians Guild?

A Yes, sir.

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Q Do you hold an office in that Guild?

A I am president of the Empire State Physicians Guild.

Q How long have you been president of the guild?

A I think four or five years.

JUDGE FEINBERG: Where is your office?

THE WITNESS: In Brooklyn. 41 Eastern Parkway, Brooklyn, New York.

Q In the course of your practice as a psychiatrist and a neurologist, do you have patients for whom you prescribe drugs that are listed on Schedule 2?

A Yes, sir.

Q What drugs are those, sir?

A The drugs primarily Ritalin, dexamine, rarely the soporifics, rarely the drugs which are used to encourage sleep. Most of the other drugs on Schedule 2 I rarely use.

Q And what are the medical and neurological conditions that are present before you will prescribe such drugs on Schedule 2 as you have just named?

A The amphetamines are used in treatment of narcolepsy. That is a condition in which the patient has an uncontrollable desire to fall asleep and will respond only to the amphetamines.

The amphetamines are also used in a condition

known as oculogyric crisis.

This is one of the sequela, one of the complications of the 1919 encephalitis epidemic which leaves the patient with various Parkinson-like symptoms and one of the rarer complications of this disease is oculogyric crisis, and when the patients have this, they lose control of the eyes, the eyes move uncontrollably in one direction or the other.

It is associated with enormous panic and anxiety. At one time it was thought to be a hysterical condition but now we know it to be organic. The exact place where the organic lesion is no one knows for sure. We have ideas. That responds to amphetamine.

Amphetamine is also used in the treatment of epilepsy. It was originally used when people were made drowsy by phenobarbital or ditantin and it was found that, paradoxically, it helped in certain patients to reduce the number of seizures.

Ritalin and amphetamine are used in the hyperkinetic disorders of childhood. There are a number of conditions which fall into or which are called the hyperkinetic disorders in childhood.

Do you want a description of that?

Q Yes.

A This is a condition which affects something like five to fifteen person of school children. It is more common in children of the deprived socioeconomic status, somewhat more common in males than in females and somewhat more common in first-born children.

They start off life with a motor disturbance. Either there is too much motility and the backs will arch up and they are brought to the breasts and this provokes a lot of anxiety in the mothers and they feel that they are being rejected, or they are flaccid.

I have written a paper on the complications of kernicterus with Dr. Alexander Weiner, the discoverer of the Rh factor, and at that time I pointed out that the children were inclined to show delayed psychomotor development, but later on, proved to be of normal intelligence.

In this paper I recognized that these kids were extremely active. I didn't have sense enough to know I was dealing with a new condition and I had no concept of what produced the activity. I think the theory at that time was all wrong.

There are other conditions now which will produce the thing and these children can't control their motor activity. They climb out of the crib much too soon

and when they begin to totter, they race around; when they walk, they are running all over the place and get into all kinds of difficulty.

In school they are so restless that they can't pay attention and often fail and then the business of failing sets up a kind of a vicious circle which disturbs them no end. I think initially they are looked upon as bad behaviors and in school they are looked upon as conduct disorders.

Paradoxically, these children do terribly when given tranquilizers. They get worse and they quiet down when they are given the mood elevators, Ritalin and dexamil.

Amphetamines are also used.

I have my own theory of why it works this way but I don't think anyone knows for sure.

These children never become the abusers of downies and uppies of adolescence. These kids who are brought up have to receive dexamil or Ritalin, otherwise they fail, and they are in a mess the rest of their lives with a high suicide rate at puberty.

As a matter of fact, you see very little of these hyperkinetic disorders recently, because the pediatricians take care of them and do a much better job

than I was able to do before we had these drugs. These are hyperkinetic disorders.

JUDGE WYATT: Can they walk without assistance? In other words, can they go from one side of the room to the other? Can they direct their movement to where they want to?

THE WITNESS: They are more mobile than the other children. The children that I described as the rarer group who start out with the disease, the kernicterus, "icterus" means yellowness, "kern" of the nucleous of the brain, and it is due to Rh sensitivity, these kids are flaccid in the period right after birth and they walk late and they sit up late and do everything late.

Then when they start walking and doing things, there is very little that you can find on neurological examination but they overdo it and they are constantly restless.

The other group of kids are hyperkinetic from birth. When the mother starts feeding them and the kids arch, that puts the mother in a tizzy and she thinks she is being rejected and they, too, continue this hyperactivity. This continues until adolescence.

Now, another place where the amphetamines and Ritalin is of value is in the schizo-affected disorders.

These patients are technically a schizophrenic but they do quite well in shock therapy or if they are treated for the depressions.

The kind of illness which is common after childbirth, patients, basically schizophrenic patients who have a great deal of hypochonrial pains, in which there is a "my back is killing me; I have a stabbing pain here or a twisting pain in the head," they do well in these depressive episodes in shock therapy but Ritalin and benzedrine are extremely efficacious in some of the patients.

I think I have covered most of the disorders which are treated.

MR. FOGARTY: If your Honors please, I don't see the need for this testimony.

The statute itself says these drugs have therapeutic value in medical use. I don't think we have to go into what they are.

JUDGE FEINBERG: I think it has gone far enough.

BY MR. LESCH:

Q Now, Doctor, in situations where triplicate prescriptions are required to be filed, do you have a practice of advising the patient?

A We have been advised that we have an obligation

to inform the patient.

Q Have you made a study or observations as to the reaction of the large number of your patients when you have advised them of the filing requirements?

A Most of them are shocked, hurt. Some of them refuse the drugs and in some patients, the schizophrenics, we are reluctant to even advise the drugs because they are suspicious enough to begin with, and they get involved with this and they worsen the condition, and we try to avoid the use of these drugs in those particular patients.

Q With respect to the patients that you actually advised of the filing requirements, can you give us a percentage of the number of patients who refused to take the drug?

A Reluctance, actual refusal, if there is a good doctor-patient relationship, they will end up accepting the drug because the doctor says so.

Q And can you give me an estimate of the number of patients who object to the filing requirements?

A I think all object.

Q Now, you said that in certain cases, you have decided not to use the drugs because of the filing requirements.

A Yes.

Q And what cases are those, mainly?

A Mainly the schizo-affected disorders who are prone to suspicion and to have me act as a putative arm of the Government in a situation like that provokes all kinds of anxiety, even delusions, and if we can avoid the use of drugs in that situation, we try to.

Q And so those are situations where you found the drug was medically indicated but because of the filing requirements you didn't use the drug?

A Yes, sir.

Q Have you ever been requested for particular drugs by addicts?

A Not too often. I have -- most of my patients are referred by other physicians and those, the addicts, are pretty well weeded out and they are easy to spot when they come in anyhow.

Q Has there ever been a situation where an addict has come to your office asking for a drug?

A On occasion, yes.

Q And have you ever prescribed for such a person whom you believed to be an addict?

A Yes, I have prescribed. Yes. They need medication but the trouble is they are taking the wrong medication.

Q Have you prescribed the drug they requested?

A Usually it is the wrong drug.

Q How can you tell whether a person is an addict when he comes to your office?

A Well, they are different types, but usually they come in with the rote story. It is a rote story, a story taken out of a textbook and usually they ask for specific medication which they know by name and dosage and it is always the story that the doctor who has always given him that drug is out of town, or something like that.

Q Doctor, you have made the statement that no ethical physican can live with this law, is that correct?

A Yes, sir.

Q Why did you make that statement?

A I made it at the annual meeting of the State Medical Society in February of 1973.

Q What was the basis for your statement?

A Well, the Commissioner of Health is an extremely fine gentleman and of the highest ethical and moral qualities but he heads a bureaucracy and I am sure working in the bureaucracy means well, but a bureaucracy is a bureaucracy.

In 1966, the Commissioner of Health of New York City notified the doctors of the city that the city law

required that they file the names of drug addicts and also said that the city law provided that these names would be confidential.

I don't know what job I had at that time. I think it was chairman of the State Committee of Mental Health, the State Medical Society, but within a short time I was told that there is a leak someplace. Specifically, a post office employee in Queens was fired from his job two weeks after he was reported.

We looked into the situation and there was no leak at the city level so the leak had to be at the state level. I asked the State Health Department if they would look into it and they were quite shocked and said they would.

Apparently, there was a state law which also demanded that the names of addicts be reported. The state law also said that the names would be kept confidential but there was a provision of the law that stated that these names were to be turned over confidentially to agents of the Federal Drug Enforcement Bureau.

I reported this to the doctors of the city.

Only recently the City Health Department has done sickle cell screening on all of its school children, particularly those who come from Mediterranean areas who

are black, and this will pick up two kinds of children, those who have the disease and those who are carriers.

Now, being a carrier doesn't mean anything. This information is put on the back of the school record where it has no business being, and we raised the dickens about that but these kids who are sickle cell carriers are now having trouble getting jobs and we learned from experience that the only way to safeguard the privacy of our patients is not to let bureaucracy get a hold of their names.

Q Doctor, you mentioned before that there was a certain category of patients, schizophrenic patients for whom you did not prescribe Schedule 2 substances even though they were indicated.

Approximately how many such patients have there been in your practice?

A Anywhere from fifteen to twenty in the last year or two.

MR. LESCH: No further questions.

CROSS-EXAMINATION

BY MR. FOGARTY:

Q Did I understand you to say that the oculogyric crisis occurs in patients who had encephalitis in 1919?

A Yes.

Q How many of those patients do you have?

A One.

Q She testified a little earlier, is that correct? Or is that someone else?

A Yes.

Q Did she testify earlier this morning?

A Yes.

Excuse me. I may have seen two or three others in the clinic.

Q How many patients do you have, total?

A How many patients do I have, total?

Q The total number of patients that you have? How many?

A You mean at the present time or since I started?

Q Right now.

A I am Chief of Service at the Brooklyn Jewish and a consultant at Brooklyn State.

What do you mean by the question, how many patients do I have?

Q How many patients are you treating at the present time?

A In my private office?

Q Let's bring it down to your private office.

A Private office, at the present time I imagine

they run anywhere from twenty to thirty a week. That includes those who come in more than once.

Q And one of them had encephalitis in 1919?

A Encephalitis in 1919 was fairly common. Oculogyric crisis is a very rare neurologic disorder.

Q All right. That is all I wanted on that.

And this patent takes a Schedule 2 drug, right?

A Amphetamines.

Q When you advise the patients about Schedule 2, what exactly do you tell them?

A What the Medical Society lawyer tells us to tell them, that your name --

Q I don't want to know about the Medical Society lawyer.

A I tell them what the Medical Society lawyer told me to tell them.

MR. FOGARTY: Objection. Your Honor, would you ask him to answer the question?

JUDGE FEINBERG: Just answer the question.

A That the name will be entered into a computer in Albany.

Q That's all you tell them?

A That there is a risk that their name may subsequently get out and if they are young children, there

is a risk that their name might be found by the Bar Association, by various state supported institutions. But the law is that the name must be entered into this computer.

Q And you relate these risks to them?

A Yes, sir.

Q And you were told by the counsel for the Medical Society to do that?

A Yes, sir.

Q You were told to relate the risks?

A Pardon?

Q You were told to relate the risks?

A Yes, sir.

Q Do you know anything about the retention period of these prescriptions?

A Since we started our suit, the state has now said it is only five years.

Q Do you tell the patients that?

A Do I tell them that?

Q Yes.

A No, sir.

Q When you treat hyperkinetic children, you write a prescription for them?

A Right.

Q Put their name on it?

A Yes, sir.

Q And if it isn't a Schedule 2 drug, do you put their name on it?

A Yes, sir.

Q Where does the name go?

A It goes in the top of the prescription.

Q And then where, what happens to it?

A The druggist, who is a professional man, has that prescription.

Q Is that available to anybody?

A There are certain people who are permitted by law to have access to such prescriptions.

Q Do you know who they are?

A I think employees of city health departments, State Health Department, Federal drug officials have access to these drugs -- have access to these prescriptions.

Q Does any more information go on the Schedule 2 triplicate prescription than goes on a regular prescription?

A No, sir.

Q Do you know what qualifications the investigators from the State Department of Health have?

A For the record, the State Health Department is

one of the finest in the country. I am sure they are well qualified.

Q Do you know what their qualification is?

A No, sir, I don't.

Q Are you aware that they have to be pharmacists?

A No, sir, I did not know that.

Q You state that no ethical physician can live with this law.

Can you explain why?

A Because you cannot expunge information from a computer, because there is no computer which cannot be gotten into, some with more difficulty than with others and I found out from experience that people mean well but you cannot trust a bureaucracy.

The only way you can keep things confidential is not to let bureaucracy have access to these names.

Q What do you mean by a bureaucracy, Doctor?

A Bureaucracy is a bureaucrat who is employed by a state or city bureau.

Q Only the state and city have bureaucracies, is that correct?

A Federal Government has it, large corporations have it.

Q How about coming down the ladder a little,

Doctor?

A Like where?

Q Let's say the Empire State Physicians Guild?

A We are kind of small compared to --

JUDGE WYATT: Isn't that just an argument, Mr. Fogarty?

MR. FOGARTY: No, it is not.

JUDGE WYATT: You are just arguing with the witness, I suggest.

MR. FOGARTY: I am sorry if you feel that way, your Honor. I will change the line.

Q How did you get into this lawsuit, Doctor?

A How did I get into this lawsuit?

Q Yes.

A You want all the details?

Q Any you care to give us.

JUDGE FEINBERG: What is the relevance of that question?

MR. FOGARTY: The relevance, your Honor, is that I don't think that the real parties in interest have been named in this lawsuit at all.

JUDGE FEINBERG: Have you made any motion along those lines?

MR. FOGARTY: No, we haven't, your Honor. But

we have a statement written by this witness.

JUDGE FEINBERG: If you want to test his credibility on cross-examination, of course you are entitled to do that.

Q Doctor, are you aware of the publication put out by the Empire State Physicians Guild, Incorporated, 11 Eastern Parkway, Brooklyn, New York?

A There were two put out: I wrote them both.

Q Are you the author of the statement, "CIBA has agreed to pick up the bill"?

A Yes, sir.

Q And is that the reason that this lawsuit was brought?

A Are you for real?

JUDGE FEINBERG: Doctor, just answer the questions.

A I'm sorry.

You want me to tell you how this lawsuit came about?

Q I asked you that originally.

A I didn't know I was supposed to answer it. Be glad to.

In 1973, February of 1973, I was a section delegate on psychiatry of the Medical Society of the State

of New York. This was discussed at this section meeting and I was instructed to bring this to the attention of the State Medical Society and to express a vehement opposition to this bill.

At the annual meeting, a meeting was arranged with a legislator responsible for this bill and the counsel to this committee.

After hearing them talk, I thought that we were in a pretty bad situation and at the annual meeting of the State Medical Society, as section delegate of the section on psychiatry, I got up and said that this is a bill with which no ethical physician could live and if the State Society wouldn't bring it into federal court that I would recommend to the Empire State Physicians Guild that we take it into federal court.

Now, it is quite possible that I felt at that time that I was an angry man and, you know, this may be a personal animosity on my part.

So the next place we discussed it, the next Medical Society meeting where this was discussed was at the executive committee of the Kings County Medical Society and it was discussed off the record.

This met the first Wednesday of March and there, too, the unanimous feeling was that this was a bad law and

we were given every encouragement.

I then wrote the Commissioner of Health of the State Health Department and asked if there was any way that this law could be written so that an ethical physician could live with it.

About six or eight weeks later, I received word that this was a legislative matter and I have to talk to the legislator.

In the meanwhile, the Guild got together and we decided to fight the bill and Mr. Perziger was instructed to start action. After Mr. Perziger started action, Professor Arthur Lynch, counsel to the Kings County Medical Society, told me that CIBA Pharmaceutical would like to pick up the tab.

After discussing this with various lawyers and various officers of various societies, we agreed to it but both of us, CIBA and we, said we would do it only if it were made public. It was made public in that announcement.

But the suit was started by, I guess, the section of psychiatry of the Medical Society of the State of New York -- no. They didn't bring the suit. I brought the suit as president of the Empire State Physicians Guild.

Q Do you know what position the State Medical

Society has taken with regard to this law?

A Do I know the position? They vigorously oppose this law and seek its repeal.

Q Is there anything in the court papers about it?

MR. JAFFE: Objection.

JUDGE FEINBERG: Sustained.

Q Did you say that in your affidavit?

A That the State Society was opposed to it?

Q Yes.

A I hold various positions but I have no authority to speak for the State Society.

Q Have you had any cases in which you have found medical indications for the use of a drug on Schedule 2 which you, yourself, have refused to use because it is on Schedule 2?

A Yes, I have one right now.

Q Where you have made the decision?

A Yes.

Q What kind of a case is that?

A She is a schizophrenic lady whom I first saw sixteen years ago. She had a rather serious depression and I put her on Ritalin, gave her shock therapy and she did very well and came back sixteen years later.

The precipitating attack this time seemed to

have been a visit with a sister with whom she had had no contact for many years. She went to visit her sister and found her sister holed up, disheveled, had not eated and there but for the grace of God could she have been and she became seriously depressed and this time I started her on shock therapy but I hated to tell a woman like this about Ritalin and that we would have to report her.

I used alternative drugs and there have been many complaints and I think this week, I am going to have to switch her to Ritalin, whether I like it or not.

Q Did you say there were alternative drugs that could be used?

A I tried them. They are not as good.

Q But this is a patient you have not told about the triplicate prescription?

A This patient? No, not yet.

JUDGE FEINBERG: Any further questions?

MR. JAFFE: No questions, your Honor.

MR. LESCH: No redirect.

JUDGE FEINBERG: Thank you, Doctor.

(Witness excused.)

M A R Y D O E, called as a witness by the Plaintiffs, being first duly sworn, testified as follows:

DIRECT EXAMINATION

BY MR. LESCH:

Q Mrs. Does, do you have any children?

A Yes, I do.

Q How many?

A Three.

Q And is one of your children being treated for or have a condition known as hyperkinesis?

A Yes.

Q And how old is that child?

A He will be 9 in January.

Q And was there a time when he received a drug for that condition?

A Yes.

Q And when was that?

A January of 1973.

Q And did there come a time when you learned about the requirements that a prescription containing your son's name for that drug would have to be filed in Albany?

A Yes, I did.

Q When did you learn that?

A I read it in the newspaper. It was sometime in the spring, before the law actually came into effect.

Q Did you then have a conversation with your son's doctor?

A Yes, I did.

Q And what did you say to your son's doctor at that time?

A I told him I didn't like the idea that my son would have to be branded for the rest of his life and that I was going to take him off the prescription, the prescribed drug, and the doctor said to me that I should think twice because he really needed the medication and it would be just like a child on insulin; if he was diabetic, would I take him off the insulin, but it was a very hard decision for me to make.

Q And --

A I tolk him off the drug, even though the doctor advised me not to.

Q What was the immediate effect on your son's conduct after you took him off the drug?

A Well, he has no -- he had no control over himself. He did very poorly in school. He was left back. He lost a full year in school because of his inability to have a long term period of concentration in the classroom.

He was disruptive. He was completely changed.

Q Have you ever permitted him to use this drug again since the law was effective?

A No, I haven't.

MR. LESCH: I have no further questions.

CROSS-EXAMINATION

BY MR. FOGARTY:

Q You used the term "branded for life."

A Yes.

Q What do you mean by that?

A Well, from what I understood with this new drug law that they had, it would have to be on his record and his record, childhood record, would go with him into adulthood and I don't want anyone ever to have the impression that my son was a drug user, for something he had no control over.

Q Who gave you this understanding of the law?

A Myself, from what I read in the newspaper.

Q You just read that in the newspaper?

A Yes.

Q Would it change your opinion if you knew that the records were only maintained for five years?

A Well, as far as I know, anything that is on your school record goes with you for the rest of your life and

you never have any type of privacy. That is something that just stays with you.

Q Does this go with your school record?

A Of course the school would have to be notified that James, my son, was on this drug, because he would have it administered to him by the school nurse.

Q How is he going to have it administered by the school nurse?

A Because it came in capsules and he was to have it so many times throughout the day.

Q And this was even before Schedule 2? This was before this law, wasn't it, that your son started on this drug?

A Yes.

Q So it is on the school record, isn't it?

A Yes.

Q Now, how did this law change anything?

A Because I didn't want him to be anything -- I didn't want him to be involved in any way with the Federal Government or in any way that would hurt him as he reached adulthood.

Q How does this law have anything to do with the Federal Government?

A Well, let's say as he got older, let's say he

wanted to get a, you know, a type of position where he would have to be investigated. This would be on his record, that at one time he was taking drugs for something he had no control over.

Q Yes, but you said it would be on the Federal records.

A Well, maybe I am a little confused as far as to what phase of the government the law is controlled but I didn't want, no matter what phase of the government this is, I don't want my son to have any kind of record at all.

Q What about the prescriptions that you were getting it on before Schedule 2?

A Well, they weren't registered, they didn't have to be registered in triplicate.

Q But they were registered with the state, weren't they?

A Yes.

Q Does it make any difference?

A Yes, it does, now.

Q Explain the difference to us, please.

A At that time, when the prescriptions were -- when I didn't read any such law in the newspaper, from what I understand, the prescription would have been treated as any normal prescription. If somebody has a toothache and they

prescribe a drug to relieve them of pain, that was it.

Now, then when they started the triplicate prescription, it would be something altogether different. My son's name would have been down there and it would have stayed for the rest of his life that at one time or another he was on a drug to help him control his emotions. And I think that is very unfair.

Q Have you heard testimony here this morning as to the length of time that this information is going to be retained?

A Yes, I did. You said five years from what I understand.

Q Is that the rest of his life?

A I don't care if you told me it was two years. I don't want any record of him having taken this drug at all.

Q Isn't there a record in the pharmacist's that he took it?

MR. LESCH: I object. I think he is arguing with the witness.

JUDGE FEINBERG: You did go over that already.

MR. FOGARTY: No further questions, your Honor.

(Witness excused.)

JUDGE FEINBERG: We'll take a short recess.

(Recess)

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S T A L N E Y I. F I S H M A N, called as a witness by the Plaintiffs, being first duly sworn, testified as follows:

DIRECT EXAMINATION

BY MR. LESCH:

Q Dr. Fishman, what is your profession, sir?

A I am a physician.

Q How long have you been a physician?

A Since 1946.

Q Do you specialize in any area of medicine?

A Internal medicine.

Do you have occasion to prescribe drugs that are on Schedule 2?

A Yes, sir.

Q Do you have a practice with respect to advising your patients when they are being prescribed a drug that is on Schedule 2?

A Either the patient or some other responsible member of the family.

Q What advice do you give the patient or the family member?

A I tell them that this is a drug which will cause their name to be entered into a record in Albany and that it will be in a computer record where it will be easily

retrievable by Government investigators.

Q Now, Dr. Fishman, at or about April of 1973, did you have a conversation with respect to one of your patient's names being entered on the computer in Albany?

A Yes, I did.

Q Without giving us the name of the patient, will you tell us what the substance of the conversation was?

JUDGE FEINBERG: Dr. Fishman's name is not on the list of witnesses in the pretrial order.

I assume there is no objection.

MR. FOGARTY: No, your Honor. We were advised of it this morning.

JUDGE FEINBERG: Are there any other changes in the list of witnesses?

MR. LESCH: That is our only change. I believe the intervenors have one.

MS. DICKSTEIN: We are not certain that George Patient will be here but we said tentatively that he would be here.

MR. LESCH: Dr. Fishman was out of town until the Thanksgiving Day holiday so that is the reason he wasn't listed.

A This particular patient is the mother of a physician, a gynecologist, and at the time that I knew the

triplicate prescription law was going to go into effect, I discussed this with the patient's son, the doctor, and told him that we ran the risk of his mother's name being exposed in a governmental record in Albany and that, did he want me to take her off the drug under those circumstances.

He felt that he would like to have his mother's name not appear in any record of the Government in Albany or elsewhere and that, moreover, if she were to find out about this, that he thought it would have an adverse effect on her health which I agreed with.

We then subsequently diminished the drug and stopped it before the law took effect.

Q What was the drug?

A Ritalin.

Q How long had she been on it?

JUDGE CARTER: I want to, before you go further, ask something:

Why, Doctor, do you feel it is necessary to advise your patients in the way that you do, that is, negatively, as you have indicated, that their name will be in Albany and that it is readily retrievable?

THE WITNESS: I feel that most of the people involved with this feel that there is a certain onus attached to having one's name on a special drug list record,

regardless of the good intentions of the Government. It implies --

JUDGE CARTER: But my question is why do you feel that you are required as the doctor to give that kind of information as to the effect of the law to your patients? That's what I want.

THE WITNESS: I think that I would have to inform them about any kind of possible adverse publicity that they might receive as a result of this drug.

Most patients are not aware of the fact that if you prescribe an ordinary drug for them that their name is going to be entered into some special record in a governmental bureau someplace.

BY MR. LESCH:

Q How long had the patient that you have been describing been on Ritalin before the conversation which her son told you that he didn't want her name entered on the computer in Albany?

A About two or three years.

Q Did you observe any effects on the patient after she was no longer taking this drug?

A Yes, I did.

Q What effects did you observe?

A She had an immediate and prompt weight gain. Her

blood pressure went back up to 190 over 110. She became bedridden.

Q Was she, after these symptoms, put back on the drug?

A No.

Q And did she take the drug at any time after the enactment of the law?

A No.

Q Excuse me. After the effective date of the section.

A Beg your pardon?

Q I meant to ask you whether she had taken the drug at any time after the effective date of the statute, which was April 1, 1973.

A No.

Q Do you have any other patients --

A Excuse me. The effective date was April 1, 1973?

Q Yes, sir.

A No. She was off of it by then.

Q Do you have any other patients who were taking Schedule 2 drugs before April 1, 1973, and have not taken them after April 1, 1973, because of the enactment of the statute?

A Yes.

Q Approximately how many such patients do you have?

A Perhaps five, ten.

MR. LESCH: I have no further questions.

CROSS-EXAMINATION

BY MR. FOGARTY:

Q Doctor, what medical societies do you belong to, professional societies?

A The American Medical Association, the Pan American Medical Association, the Medical Society of the State of New York, the American College of Physicians, the American College of Cardiology, the American College of Chest Physicians, the National Medical Veterans Society.

Brooklyn Society of Internal Medican, New York Cardilogical Society. American Thoracic Society, New York Trudeaux Society.

There may be others, sir.

Q Is the Empire State Physicians Guild one of them?

A No, sir.

Q Now, you made a statement that this information is easily retrievable.

A Yes, sir.

Q Where did you get that information?

A I understand that --

Q Where did you get the information that this --

A I understand that the information goes into a computer. I assume it is easily retrievable.

Q You assume that?

A Yes, sir.

Q On what basis do you assume that?

A I have some knowledge of how easy it is to retrieve information from a computer. I think that is general knowledge.

Q Do you have any information as to the computers that are being used by the State Department of Health?

A Information as to what kind of computers the State Department of Health is using?

Q Yes.

A No, sir, I don't.

Q Do you know anything about their system?

A No, sir, I don't.

Q So that it is purely an assumption on your part?

A I think it is common knowledge how quickly one can get information from a computer, sir.

Q How do you get information from a computer, Doctor?

A The person who is in charge of retrieving that information presses a button and it comes out in short order.

Q That's it?

A Yes, sir.

Q And there is nothing more complicated than that?

A That is my experience with airlines, credit cards, any other computer setup.

Q All you do is push buttons?

A Yes, sir.

Q Do you know anything about terminal systems in computers?

A A little bit.

Q Is there any terminal system in the New York State Medical Department?

A New York State Health Department?

Q The Health Department.

A I don't know.

Q Pardon me?

A I don't know.

Q Is it possible to get information out of a computer if it isn't in there?

A Out of a computer if the information is not in the computer?

Q Yes, sir.

A Not as far as I know.

MR. FOGARTY: Thank you. No further questions.

JUDGE FEINBERG: Thank you, Doctor.

(Witness excused.)

MR. LESCH: Dr. Schmierer.

I S R A E L S. S C H M I E R E R, called as a witness by the Plaintiffs, being first duly sworn, testified as follows:

DIRECT EXAMINATION

BY MR. LESCH:

Q Doctor, what is your profession?

A I am a physician licensed to practice medicine in the State of New York.

Q How long have you been a physician so licensed?

A Since 1928.

Q Will you give us your educational background, sir?

JUDGE FEINBERG: Will the parties stipulate as to the Doctor's education background?

MR. FOGARTY: I will, your Honor.

MR. LESCH: And also as to his postgraduate training.

JUDGE FEINBERG: I assume you will enter into the record a statement of his education background and the postgraduate training, to which the State will stipulate.

MR. FOGARTY: Yes, sir. We will stipulate to what is in the affidavit that he prepared in the original papers, your Honor, and I think that is more than adequate.

Q What is the Empire State Physicians Guild, Dr. Schmierer?

A It is a socioeconomic group of physicians organized about thirty or thirty-five years ago which will be interested in certain problems confronting the physician, certain problems that the County Medical Society cannot deal with and it is thrown into the lap of the Empire State or the Physicians Guild.

Q Do you hold a position with that organization?

A At the present time I am Chairman of the Board of Governors of the Physicians Guild.

Q What type of socioeconomic problems does it concern itself with?

A Well, we watch legislation in Albany which might be harmful to the physician. We try to watch and prevent people who don't have licenses to practice medicine, keep them from practicing medicine, such as unions, hospitals and so forth.

Q Doctor, in the course of your practice, do you prescribe drugs on Schedule 2?

A Yes, sir.

Q And did you do so prior to April 1, 1973?

A Yes, sir.

Q Have you at my request made a study in order to

determine whether the number of patients for whom you are prescribing Schedule 2 drugs has decreased since the effective date of the law, April 1, 1973?

A Yes, I have.

Q And can you tell us whether there has been a decrease? Has there been such a decrease?

A Yes, sir.

Q Approximately what percentage decrease has there been?

A I went over my records last night and of about sixteen patients to whom I gave Ritalin this year, only about five or six have continued to use it.

JUDGE WYATT: What is Ritalin prescribed for, Doctor?

THE WITNESS: For hyperkinetic children, children who have terrific behavior problems, short attention span, cannot learn, are very difficult to control.

Q And have you ascertained the reason why there has been this decrease from sixteen to six?

A For the simple reason that the patient will note that she is getting a different type of prescription than I ordinarily write and, of course, I do inform her that this is a, what is called a triplicate prescription which must be--a copy of which will be kept in Albany which will be a

permanent copy for a certain length of time.

Q And have those patients who have refused to continue the use of Ritalin indicated the reason why they have so refused?

A Simply -- I shall restate the words that I heard here this morning -- that they do not want any type of permanent record against their children.

Q Is that what the substance of what they have all said to you is?

A Yes, sir.

Q Are any of the children for whom you have prescribed Ritalin addicted to that drug?

A No, sir.

Q Can you tell when a person is an addict?

A Yes, sir.

Q How can you tell that?

A Well, those -- I specialize in pediatrics. I do only pediatrics and when an adolescent, an older adolescent or an adult will walk in my office, he almost admits he is an addict and, of course, I always turn him down, send him away, that I do not treat adults and, of course, they practically admit they are addicts.

MR. LESCH: I have no further questions.

CROSS-EXAMINATION

BY MR. FOGARTY:

Q Doctor, what is your basic objection to the triplicate prescription law?

A The mere fact that the confidentality between myself and the patient is being violated, the mere fact that the patients know this and they are refusing to use a drug which is extremely beneficial to these children and the few patients that have continued admit that they know that there is a record but they say they cannot help it, that they must continue using it.

Q In other words, your basic objection is the placing of the identity of the patient?

A Yes, sir.

Q Doctor, did you prepare an affidavit at the outset of this litigation?

A I probably did. I do not recall at the moment.

Q On the 28th of March 1973?

A I couldn't recall back that far.

Q I show you a copy of an affidavit attached to the original papers served on the Attorney-General.

A That's right. Yes, sir.

Q You read and signed that affidavit, is that correct?

A Yes.

Q And you are still concerned about the confidentiality of your patients, is that correct?

A Yes.

Q Would you tell us why you put the names of two children in that affidavit?

A Well, I didn't make up this affidavit. I certainly did sign it so I think this may have been a faux pas on the part of the people who made this application up.

MR. LESCH: This has already been explained to the Attorney-General's Office, that it was an error at the time that the affidavit was prepared, as to which we are embarrassed.

Q Now, you explain to your patients about the triplicate law.

What do you tell them exactly?

A I inform them that I must issue to them a very special type of prescription. It is not -- doesn't come off the usual prescription pad and, of course, they will question me and I do explain to them that one copy of this will go to Albany and will be a permanent record.

Q You tell them it will be a permanent record?

A I use the word permanent. I didn't qualify that

it would be five years. I said it would be a permanent record.

Q Why don't you qualify it for five years?

A For the simply reason I didn't know exactly at that time how long these records would be kept.

JUDGE WYATT: Is there any dispute between the parties that, as the State has said this morning, the State destroys the records after five years?

MR. JAFFE: Your Honor, as far as I am concerned, there is certainly a dispute because my experience with attempting to reclaim records from such sources as the FBI, finding that I have to file a copy and then finding later that the same records are reproduced, I have my doubts that five years hence that those tapes will be fully destroyed and there is definitely, in that sense, some dispute.

JUDGE WYATT: Tell me, where is the direction to destroy the records after five years?

MR. FOGARTY: It is contained in Section 33 --

JUDGE WYATT: It is in the statute?

MR. FOGARTY: In the statute, your Honor.

JUDGE FEINBERG: An amendment to the statute.

MR. FOGARTY: A1974 amendment to the statute. Section 3370.3 and it states that the Department shall cause to be expunged or otherwise destroyed within five years from

the date of receipt thereof any record of the name of any patient received by it pursuant to the filing requirement.

MR. JAFFE: As the Court --

JUDGE FEINBERG: Excuse me, please.

Mr. Jaffe stated that his problem with that is that he has some doubts whether at the end of the five years that direction will be carried out.

I am not suggesting that it will or will not but do I understand it, following up Judge Wyatt's question, that there is no dispute that the statute as written applies to destroying all records including the material on the computer tapes?

MR. LESCH: That is not quite correct.

The statute, as written, refers to any record received by the State and it is possible that the statute could be interpreted to mean that the triplicate prescription form would be destroyed but the information that is on the computer tape which is not a record that is received by the State from anyone else would not be destroyed.

JUDGE FEINBERG: So you are taking the position that you are not sure that the statute requires the expunging of the names of patients already on the computer tape.

MR. LESCH: Yes, we are taking that position.

JUDGE FEINBERG: I see at this point no need for us to have further legal argument.

MR. LESCH: And I also point out, your Honor, that this statute was passed on June 13, 1974, and I think that it will be conceded by the State that it was as a result of this lawsuit that they passed the statute.

JUDGE FEINBERG: Gentlemen, we have already interrupted Mr. Fogarty's cross-examination.

Do you have an extra copy of the statute and, if so, would you pass it up.

Go ahead, Mr. Fogarty.

MR. FOGARTY: May I have the last question.

(Question read.)

BY MR. FOGARTY:

Q Is it your intention to include that caveat in future instructions?

A Yes, yes.

Q In other words,you will?

A If I am assured by my attorneys that these records will definitely be destroyed at the end of five years.

Q Have you reason to believe they won't?

A I don't know.

Q Now, with regard to changing of your prescription habits, how did you come to that conclusion, Doctor?

JUDGE CARTER: What was the question?

A Sir, I have not changed my prescribing habits at all.

JUDGE WYATT: Excuse me. The Judge wanted to hear the question.

(Question read.)

A I have not changed my prescribing habits. I still prescribe the drugs with the patient's permission. I urge them to permit their children to take this drug.

However, if they have serious objections because of the prescription, there is nothing I can do but hand them a prescription. Whether or not they fill it, I don't know.

Q With a normal prescription blank, do you ever advise your patients that that information is available to the State Department of Health?

A No, I do not.

Q Any reason for that?

A There is a certain maount of confidentiality between the pharmacist and the patient and, as a matter of fact, I read in the papers just one or two days ago that

there is going to be some laws passed not permitted anybody at all to walk into a pharmacy and inspect prescriptions, any prescriptions, unless he is qualified or has a good reason for it.

Q Are you aware of the confidentiality provisions of this law?

A No.

JUDGE WYATT: You mean the law in suit?

MR. FOGARTY: Yes, your Honor.

Q You are not aware of Section 3371 of this law?

A No.

Q Entitled "Confidentiality of Certain Records, Reports and Information"?

A How do I know that the confidentiality will be observed?

Q How do you know that the confidentiality of the patient and the pharmacist will be observed, Doctor?

A I feel I can trust the pharmacist.

Q You can trust the local pharmacist?

A Yes, sir.

Q You can trust State officials?

A I don't know who they are. I am not familiar with them.

Q You don't know any of them?

A No, I don't know any of the State officials.

Q And you presume that they are violating the law constantly?

A I don't presume that at all.

MR. LESCH: Objection.

JUDGE FEINBERG: The witness already answered it and Mr. Fogarty is going to go on to something else.

MR. FOGARTY: Sorry, your Honor. I thought you were talking to me.

No further questions.

MR. JAFFE: I have no questions.

MR. LESCH: No further questions.

JUDGE FEINBERG: Thank you, Doctor.

(Witness excused.)

GEORGE PATIENT, called as a witness by Co-Plaintiffs, being first duly sworn, testified as follows:

DIRECT EXAMINATION

BY MR. JAFFE:

Q Mr. Patient, what is your occupation?

A Unemployed at the present time.

Q And why are you unemployed?

A Disability.

Q What is that disability?

A Cancer of the lung and removal of the ribs.

Q And have you had an operation which relates to that?

A Two.

Q When were those operations?

A The one on the lung was five years this past September and on the ribs three years this coming February.

Q Now, as a result of those operations and this condition, do you or have you taken drugs?

A Yes, sir.

Q And what drug do you principally use?

A Percodan.

Q Did there come a time when you were informed that the way in which Percodan would be prescribed was changing?

A Yes, sir.

Q Your physician told you that, is that correct?

A Yes, sir.

Q And what did your physician tell you?

A I would be on record in Albany as a drug abuser.

Q What was your reaction to that?

A I didn't like it at all.

Q Did you attempt substitute drugs as a result of this?

A Yes, sir.

Q And what drugs were those?

A Tylenol 3; codeine with aspirin.

Q Did those drugs work for you?

A No, sir.

Q In what sense did they not work?

A Well, they never relieved the pain.

Q You have continuing pain without Percodan?

A Yes, sir.

Q And after you attempted to substitute those drugs, and they were unsuccessful, what did you do?

A I didn't hear it, sir.

Q Did you have Percodan prescribed for you after this time?

A Yes, sir.

Q Was it prescribed on triplicate prescription?

A At times it was. By different doctors.

Q How do you presently obtain the drug?

A Through a union form and out of state.

Q In other words, you go out of state to get the drug at this point?

A Yes, sir.

Q Is that a result of this law?

A Yes, sir.

MR. JAFFE: I have no further questions.

CROSS-EXAMINATION

BY MR. FOGARTY:

Q Sir, who told you you were going to be listed as a drug abuser?

A Well, it is a narcotic and I figured --

Q Sir, just a moment, please.

Who told you you were going to be characterized as a drug abuser?

A I don't follow you.

Q You said that you didn't want your name going into a computer as a drug abuser.

A I didn't mention computer at all. I said I just didn't want to be on record.

Q As a drug abuser is what you said.

A That's right.

Q Who said you would be a drug abuser?

A Well, I would be, wouldn't I?

Q Who told you that?

A I don't follow.

MR. JAFFE: His original testimony was that he was told he would be on record. The conclusion, as he indicated, was that he would be on record as a drug abuser and so the question is not exactly apt.

JUDGE WYATT: I understood him to say, and my

recollection may be at fault here, he was told that he would be on record as a drug abuser.

MR. FOGARTY: That is my recollection if it, your Honor.

JUDGE WYATT: And I wonder about it.

MR. JAFFE: I just object to the form of the question, your Honor.

JUDGE FEINBERG: In any event, the witness now knows what the question is.

The question is, who told you that you would be listed as a drug abuser?

THE WITNESS: My doctor.

Q What doctor?

A Dr. Lustig.

Q He used that term? You need this drug for your condition, don't you?

A Yes, sir.

Q And Dr. Lustig prescribes it?

A That's right.

Q And you get it at the pharmacy without any problem?

A Not locally.

Q Do you have problems with the local pharmacy?

A Dr. Lustig does not use the new form.

Q He doesn't use them at all?

A Not to me, he doesn't.

Q Why doesn't he use them with you?

A I don't think he uses them with anybody.

Q Why don't he use them with you?

A I don't know. He hasn't used them --

Q Did you tell him you didn't want them?

A Pardon?

Q Did you tell him not to use them?

A Did I tell him not to use the forms? No, sir.

Q There is no reason why he can't give you a prescription on a triplicate form, is that correct?

A He may have other ideas of it; I don't know.

Q But you are his patient?

A Yes, I am.

Q And you cannot exist without, at least in your own view, you cannot exist without Percodan?

A That's right.

Q But you haven't been told by anybody that you can't get it in the State of New York legally?

A That I what?

Q Nobody has told you that you cannot get Percodan in the State of New York legally?

JUDGE CARTER: Isn't this a waste of time? He has

testified as to why he is going outside of the state.

MR. FOGARTY: No further questions.

MR. JAFFE: I just have one question.

REDIRECT EXAMINATION

BY MR. JAFFE:

Q You did tell Dr. Lustig that you did not wish to be on record in Albany, isn't that right?

A That's correct.

MR. LESCH: And may I have one question.

REDIRECT EXAMINATION

BY MR. LESCH:

Q After you told that to Dr. Lustig, did he then give you the forms which enabled you to get your Percodan in New Jersey?

A That's right. On my union forms. They pay for the medication.

MR. LESCH: Thank you.

JUDGE FEINBERG: Anything else?

RECROSS EXAMINATION

BY MR. FOGARTY:

Q You said union forms. Do you get reimbursement from your insurance company on your prescription?

A If I pay for them, I get them reimbursed.

Q So the insurance company is aware of the Percodan?

MR. JAFFE: Objection. He testified he did not pay for them.

JUDGE FEINBERG: Overruled.

Q Who pays for them?

A The union.

Q Then you tell them that you take Percodan?

A Certainly the know I take Percodan. It is on record.

Q That is a record of it, right? A public record?

MR. LESCH: Objection. I object to the question.

JUDGE FEINBERG: Rephrase it.

Q That is a record of it, correct?

A It goes to a certain plan which the union has. The union pays this plan for the medication that I take.

Now, as far as the union, no, it does not know what medication I take. It is the plan that the union has.

Q You don't tell, you never tell the union what drugs you are taking? They just pay you money, is that the idea?

A Pardon? They knew the operations I went through.

Q Pardon me?

A They knew the operations I went through. They knew what it was for.

Q Your doctor knows, too.

Do they know what drugs you are taking?

A I guess they probably do, because they pay the bill.

MR. FOGARTY: Thank you very much.

JUDGE FEINBERG: Thank you, sir.

(Witness excused.)

JUDGE FEINBERG: Any further witnesses for plaintiffs?

MR. JAFFE: Yes, your Honor. One more witness. In fact, your Honor, I think we have two more witnesses but one is to be after lunch.

G E R A L D L. L U S T I G, called as a witness by the Co-Plaintiffs, being first duly sworn, testified as follows:

DIRECT EXAMINATION

BY MR. JAFFE:

Q Will you state your educational and professional background to the Court?

A Yes. I am a thoracic and cardiovascular surgeon or chest and heart surgeon.

I have by Boards in the American Board of Surgery, The American Board of Thoracic and Cardiovascular Surgery. Member of the American College of Surgeons.

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I am also a member of many other professional organizations, in addition to which I am president of the Richmond County Medical Society and president of the New York State Federation of Physicians and Dentists and I am vice president of the American Federation of Physicians and Dentists.

Q As a surgeon, do you have occasion to prescribe what are now known as Schedule 2 drugs?

A Very often.

Q And which drugs are those?

A We use Demerol, morphine, codeine, Percodan, Hycodan and drugs of that nature.

Q And how long have you been prescribing drugs of this nature?

A Ever since I graduated from medical school in 1948.

Q And in what connection do you use those drugs?

A Well, chest surgery, first of all, in some of the preoperative orders that we render, we use these drugs and in the postoperative orders for pain and other difficulties of that nature, we prescribe the narcotics.

Q Since April 1973, when this law came into effect, have you been prescribing these drugs?

A I have in the hospital only.

Q And in the hospital you do not fill out what is called a triplicate prescription form, is that correct?

A We do not.

Q And you have not been filling out the triplicate prescription form since 19 -- in your private practice?

A I do not.

Q And why do you not do that?

A In medical school and since that time, the relationship of patient and doctor has been one that's been pretty well described and I feel that personally I cannot abide by the confidentiality factors related to the triplicate prescription law.

Q So you do not prescribe these drugs in private practice?

A I do not.

Q It is true, however, that you prescribe -- there is one exception to this?

A Yes.

Q Namely, George Patient?

A Yes.

Q Now, have there been occasions on which these drugs have been in your private practice medically indicated?

A Yes, frequently.

Q What do you do in those instances?

A Well, first of all, I attempt to use such things as -- interestingly enough, Percodan is part aspirin and Codenone, which is synthetic, and I use aspirin or Tylenol and codeine which is allowed to be prescribed under the BNDD prescription, Federal Narcotic License.

Q In other words, that is a drug as heavy in codeine as codeine is itself?

A Not terribly heavy and neither is Percodan a heavy narcotic drug.

Q And have you found that these substitutes are adequate?

A They have to be or else I refer them to other physicians who have the capability of using stronger medication under the triplicate prescription.

Q How long may you or have you on occasion tried these substitute drugs for?

A The only ones that I prescribe except in --

JUDGE CARTER: I am sorry. I don't understand the question. The last question. The question before that, I mean.

You said you refer them to physicians?

THE WITNESS: I refer them to other physicians who have the capability or who have the triplicate

prescription forms. In principle, I don't use them because I am opposed to the triplicate prescription.

JUDGE CARTER: In other words, you mean you refer them to physicians who are following the law as now prescribed, is that right?

THE WITNESS: Who follow the law with the triplicate prescription, yes, sir.

JUDGE CARTER: That is what I didn't understand.

BY MR. JAFFE:

Q Often you attempt substitutes and if it does not work, you refer them.

How long may this period in which you attempt substitutes go on before the referral period?

A In most postoperative patients, you are able to carry these patients along for a period of time, say two to three weeks. Beyond this period of time, it is quite possible that these patients can get along on such things as empirin and codeine -- I mean empirin, anacin and aspirin, things of this sort.

Once in a while they need a little additive but in general, they phase out and in certain types of operations, as Mr. Patient had, where ribs are removed, they have arthritic changes which involve the nerves between the ribs and this is called intercavital neuralgia where the

pain associated with the nerves between the ribs being pinched or arthritic changes taking place.

In those situations, it is very difficult to control this in general.

Now, Mr. Patient has had good relief with Percodan. Occasionally he gets a cough, which requires Hycodan, another drug that is on the Schedule 2, but in the meantime, he is not, in his own way, able to get along with the empirin and codeine or Tylenol and codeine.

Q In other words, as a result of the practice of substitution, a patient may undergo pain for a period of time, attempting to find substitutes, is that correct?

A Yes.

Q And this in your case results from your feeling that the law has changed the structure of confidentiality?

A I feel that way.

Q Have you run into other physicians throughout the state who have felt the same way?

A I travel throughout the country and the state speaking to various doctor's groups and medical societies by nature of my position and I have found that anywhere from ten, fifteen, sometimes twenty or thirty percent of doctors do object; sometimes they don't have the background for their objection, but many of them are very firmly

convinced as I am and as when most of us have been trained, that confidentiality is a very important factor between a patient and his physician.

Q And I take it that both in your practice and in theirs, they have changed their medical practice as a result of this law?

A There are about, anywhere from ten to fifteen or twenty percent of doctors in various areas who do not use that triplicate prescription. I know that to be true on Staten Island.

MR. JAFFE: No further questions.

CROSS-EXAMINATION

BY MR. FOGARTY:

Q Doctor, when you use substitutes for the Schedule 2 drugs, is it safe to assume that there is no medical impairment or danger to the patient?

A I would never endanger the patient under any circumstances, so, of course, that would be true.

Q I didn't think you would.

A That would be true.

Q So that in a lot of these cases, they probably can get by on something else?

A I have stated that.

Q Did you hear your patient testify that you have

him prescriptions to be filled somewhere else?

A He by accident found out that his union prescriptions, as such, can be filled out of state. He sometimes goes to Florida or he has gone to Michigan and he has gone to Jersey and found out that his union -- I do not maintain those forms -- he has the forms and he has them filled on those forms.

Q In other words, you don't --

A I do not maintain those forms.

Q And you don't --

A The only forms I maintain are the customary Prescription pads that we have had for many years.

Q And you do not prescribe Schedule 2 drugs?

A No, sir.

MR. FOGARTY: Thank you very much, Doctor.

JUDGE FEINBERG: Thank you, Doctor.

(Witness excused.)

JUDGE FEINBERG: Next witness.

MR. JAFFE: Your Honor, we had one witness for, to be frank, two o'clock, inasmuch as we didn't think we would be through with all of these witnesses.

JUDGE FEINBERG: Who is that?

MR. JAFFE: Another pediatrician who will testify that he has had a drop in the --

JUDGE FEINBERG: Would you give the name?

MR. JAFFE: Dr. David Kane.

JUDGE FEINBERG: That is your one remaining witness?

MR. LESCH: We have one witness also.

MR. JAFFE: That is my remaining witness.

MR. LESCH: Our witness is Mr. Robert Roe, who is a school teacher, who said that he would get here about three o'clock.

MR. FEINBERG: How about the defendant's witnesses? Are they here?

MR. FOGARTY: The are taken on deposition, your Honor.

JUDGE FEINBERG: Is Dr. Kane going to give any information other than what we have already had from four doctors?

MR. JAFFE: I would say fundamentally not different, your Honor, to be frank.

JUDGE FEINBERG: How about Mr. Roe?

MR. LESCH: Well, your Honor, perhaps we can do it by stipulation. I don't think the State would --

JUDGE FEINBERG: Can't you stipulate that if Mr. Roe came to testify, he would testify in the following manner -- and read it into the record? What would Mr. Roe

testify to?

MR. LESCH: That he is the father of a nine-year old boy, that his son's condition was diagnosed approximately three years ago, that he has been treated by a doctor who has prescribed Ritalin, that he has a 145 I.Q., that prior to his treatment with Ritalin, he was performing well below grade level, that since Ritalin has been prescribed, the boy has been performing at or above his grade level, that when he first learned about the triplicate prescription requirements that he objected to the filing of the prescriptions, but that he was advised by the doctor that it was necessary for his son's continued well being and that he objected strenuously to the filing requirement but because it was necessary for his son's well being, he hasn't taken his son off and that his son is now receiving Ritalin, that prescriptions covering his son's prescription are filed in Albany and that he continues to object to this procedure.

JUDGE FEINBERG: Would you say that it is a fair characterization that that testimony would be fairly similar to some of the other testimony that we have had?

MR. LESCH: Yes.

JUDGE FEINBERG: Other witnesses for plaintiff?

MR. LESCH: Yes, I would.

JUDGE FEINBERG: And Mr. Fogerty, would you be willing to stipulate that if Mr. Roe were so called that that is what he would testify to?

MR. FOGARTY: With the one caveat, your Honor, that on cross-examination he would admit that the school records contain his child's condition.

MR. LESCH: I don't know that to be a fact.

MR. FOGARTY: Well, I am the father of five and I know they are there.

JUDGE FEINBERG: Well, gentlemen --

MR. FOGARTY: Off the record, your Honor. I get a blank every September that asks me all the conditions of my children and I have to give it to them; that's all. That is the public schools.

JUDGE FEINBERG: Gentlemen, do you want to accept that testimony by stipulation of Mr. Roe, that that is what he would testify to and that he would be cross-examined along those lines, without any stipulation as to what he would admit? That's how he would be cross-examined.

MR. FOGARTY: All right. That is all right.

MR. JAFFE: I would like to say on the documents --

MR. LESCH: That is agreeable to us.

MR. JAFFE: That is agreeable to us.

On the Doctor's testimony, your Honor, he would

testify that there are children who have been off the drug as a result of this law for a period of time and it has a detrimental effect on their schooling and that he has dealt with particular cases of that sort and it has hurt the children as a result of the parents feeling that the law had changed the nature of the prescribing process and the record would hurt their children.

JUDGE FEINBERG: Would you regard that testimony as essentially cumulative to what we already have of the four doctors?

MR. JAFFE: Your Honor, I think the question would be better put, does the Court consider it cumulative. I am not sure I am the final arbitrator here.

JUDGE FEINBERG: I don't want to exclude the testimony unless we have this. Could we have a stipulation that that is what the doctor would testify to?

MR. FOGARTY: I would stipulate that it would be cumulative. We have heard it before.

JUDGE FEINBERG: Do you have any objection to the statement for the record that that is what he would testify to and we would take it that wya or do you want the opportunity to cross-examine?

MR. FOGARTY: No. I would stipulate that the cross-examination would be the same as earlier witnesses.

JUDGE FEINBERG: Then the taking of evidence by live witnesses is closes, gentlemen, is that correct? And the deposition testimony has to be submitted to us.

MR. FOGARTY: That's right.

JUDGE FEINBERG: But the taking of evidence by this Court, of live witnesses, is closed.

MR. LESCH: Yes, your Honor.

MR. FOGARTY: Yes, your Honor.

(Discussion off the record.)

JUDGE FEINBERG: The hearing, then, is closed and we will await whatever further has to be submitted to us and thank you very much.

(Court adjourned.)

Deposition of Dr. Joseph Martin Rosenberg.

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

- x

RICHARD ROE, an infant, by ROBERT ROE, his parent, JOHN DOE, an infant, by MARY DOE, his parent, JAMES MOE, an infant, by MICHAEL MOE, his parent, JANE POE, MATTHEW T. BRODY, ISRAEL L. SCHMIERER and EMPIRE STATE PHYSICIANS GUILD, INC.,

Plaintiffs,

-and-

GEORGE PATIENT, MARTHA PATIENT, GERALD L. LUSTIG and THE AMERICAN FEDERATION OF PHYSICIANS AND DENTISTS,

Additional Plaintiffs,

-against-

HOLLIS S. INGRAHAM as Commissioner of Health of the State of New York,

Defendant.

INDEX NO.
73 CIV 1303
(RLE-3 Judge Court)

- x

Deposition of DR. JOSEPH MARTIN ROSENBERG, a witness, taken by plaintiffs pursuant to order, at the offices of Messrs. Shea, Gould, Climenko & Kramer, 330 Madison Avenue, New York, N. Y. 10017, on December 4, 1974, at 10:00 a.m., before William Blitz, a Certified Shorthand Reporter and Notary Public of the State of New York.

BEST COPY AVAILABLE

APPEARANCES:

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Of Counsel

ALSO PRESENT:

AMBROSE P. DONOVAN, JR., ESQ.

JOSEPH BONACCI

JOSEPH L. CANNIZZARO

oOo

IT IS HEREBY STIPULATED AND AGREED, by and between the attorneys for the respective parties herein, that the sealing, filing and certification of the within deposition be waived; that such deposition may be signed and sworn to before any

officer authorized to administer an oath, with the same force and effect as if signed and sworn to before the officer before whom said deposition is taken.

oOo

MR. LESCH: I ask that there be marked Sample Triplicate Prescription Form (Deposition Exhibit 23) as Plaintiffs' Trial Exhibit 1 for identification.

(Sample Triplicate Prescription Form (Deposition Exhibit 23), marked Plaintiffs' Trial Exhibit 1 for identification as of this date.)

MR. LESCH: I ask that there be marked a chart entitled "Phase II: Practitioner Rx Work Flow Chart" (Deposition Exhibit 1) as Plaintiffs' Trial Exhibit 2 for identification.

(Chart entitled "Phase II: Practitioner Rx Work Flow Chart" (Deposition Exhibit 1), marked Plaintiffs' Trial Exhibit 2 for identification as of this date.)

MR. LESCH: I ask that there

be marked the same document as Exhibit 2, with additional material (Deposition Exhibit 17) as Plaintiffs' Trial Exhibit 2A for identification.

(Same document as Exhibit 2, with additional material (Deposition Exhibit 17), marked Plaintiffs' Trial Exhibit 2A for identification as of this date.)

MR. LESCH: I ask that there be marked a document entitled "Phase II: Practitioner Rx Nacro Flow Chart B" dated 8/7/73 (Deposition Exhibit 3) as Plaintiffs' Trial Exhibit 3 for identification.

(Document entitled "Phase II: Practitioner Rx Nacro Flow Chart B" dated 8/7/73 (Deposition Exhibit 3), marked Plaintiffs' Trial Exhibit 3 for identification as of this date.)

MR. LESCH: I ask that there be marked the same document as Exhibit 3, but dated 11/29/73 and containing additional material (Deposition Exhibit 18), as Plaintiffs' Trial Exhibit 3A for identification.

(Same document as Exhibit 3, but dated 11/29/73 and containing additional material (Deposition Exhibit 18), marked Plaintiffs' Trial Exhibit 3A for identification as of this date.)

MR. LESCH: I ask that there

be marked a document entitled "Schedule II Controlled Substances System, Draft 9/14/73 Phase II: System Update - Filled Prescription-Practitioners (Phase II Practitioner/Rx Work Flow Chart)" (Deposition Exhibit 3) as Plaintiffs' Trial Exhibit 4 for identification.

(Document entitled "Schedule II Controlled Substances System, Draft 9/14/73 Phase II: System Update - Filled Prescription-Practitioners (Phase II Practitioner/Rx Work Flow Chart)" (Deposition Exhibit 3), marked Plaintiffs' Trial Exhibit 4 for identification as of this date.)

MR. LESCH: I ask that there be marked a document entitled "Reported Missing Practitioner Rx's Which Have Been Filled" (Deposition Exhibit 4, 11) as Plaintiffs' Trial Exhibit 5 for identification.

(Document entitled "Reported Missing Practitioner Rx's Which Have Been Filled" (Deposition Exhibit 4, 11), marked Plaintiffs' Trial Exhibit 5 for identification as of this date.)

MR. LESCH: I ask that there be marked a document entitled "Practitioner Prescription Criteria Deviations" (Deposition Exhibit 4A, 11A) as Plaintiffs' Trial Exhibit 6 for identification.

(Document entitled "Practitioner Prescription Criteria Deviations" (Deposition Exhibit 4A, 11A), marked Plaintiffs' Trial Exhibit 6 for identification as of this date.)

MR. LESCH: I ask that there be marked a document entitled "Practitioner Rx Transaction Record Edit Error Listing (Asterisk Indicates Error)" (Deposition Exhibit 4B, 11B) as Plaintiffs' Trial Exhibit 7 for identification.

(Document entitled "Practitioner Rx Transaction Record Edit Error Listing (Asterisk Indicates Error)" (Deposition Exhibit 4B, 11B), marked Plaintiffs' Trial Exhibit 7 for identification as of this date.)

MR. LESCH: I ask that there be marked a document entitled "Procedure for Daily Editing of Triplicate Prescriptions" (Deposition Exhibit 5) as Plaintiffs' Trial Exhibit 8 for identification.

(Document entitled "Procedure for Daily Editing of Triplicate Prescriptions" (Deposition Exhibit 5), marked Plaintiffs' Trial Exhibit 8 for identification as of this date.)

MR. LESCH: I ask that there be marked a document entitled "Identification

Division, Program-ID. 'H66034'" (Deposition Exhibit 6) as Plaintiffs' Trial Exhibit 9 for identification.

(Document entitled "Identification Division, Program-ID. 'H66034'" (Deposition Exhibit 6), marked Plaintiffs' Trial Exhibit 9 for identification as of this date.)

MR. LESCH: I ask that there be marked a Xerox copy of a handwritten document showing printouts to be prepared monthly (Deposition Exhibit 8) as Plaintiffs' Exhibit 10 for identification.

(Xerox copy of a handwritten document showing printouts to be prepared monthly (Deposition Exhibit 8), marked Plaintiffs' Trial Exhibit 10 for identification as of this date.)

MR. LESCH: I ask that there be marked a document entitled "Schedule II Controlled Substances System, Phase II: System Update - Filled Prescription-Practitioners (Phase II Practitioner/Rx Work Flow Chart)" with attachments (Deposition Exhibit 10) as Plaintiffs' Trial Exhibit 11 for identification.

(Document entitled "Schedule II Controlled Substances System,

Phase II: System Update - Filled Prescription-Practitioners (Phase II Practitioner/Rx Work Flow Chart)" with attachments (Deposition Exhibit 10), marked Plaintiffs' Trial Exhibit 11 for identification as of this date.)

MR. LESCH: I ask that there be marked a live of five computer programs using data from the filled prescriptions (Gottheim 58) as Plaintiffs' Trial Exhibit 12 for identification.

(List of five computer programs using data from the filled prescriptions (Gottheim 58), marked Plaintiffs' Trial Exhibit 12 for identification as of this date.)

MR. LESCH: I ask that there be marked Program No. 1 as Plaintiffs' Trial Exhibit 12A for identification.

(Program No. 1, marked Plaintiffs' Trial Exhibit 12A for identification as of this date.)

MR. LESCH: I ask that there be marked Program No. 2 as Plaintiffs' Trial Exhibit 12B for identification.

(Program No. 2, marked Plaintiffs' Trial Exhibit 12B for identification as of this date.)

MR. LESCH: I ask that there be marked Program No. 3 as Plaintiffs' Trial

Exhibit 12C for identification.

(Program No. 3, marked Plaintiffs' Trial Exhibit 12C for identification as of this date.)

MR. LESCH: I ask that there be marked Program No. 4 as Plaintiffs' Trial Exhibit 12D for identification.

(Program No. 4, marked Plaintiffs' Trial Exhibit 12D for identification as of this date.)

MR. LESCH: I ask that there be marked Program No. 5 as Plaintiffs' Trial Exhibit 12E for identification.

(Program No. 5, marked Plaintiffs' Trial Exhibit 12E for identification as of this date.)

MR. LESCH: I ask that there be marked a printout entitled "Practitioner Rx Transaction Record Edit Error Listing" (Cannizzaro 83-86) as Plaintiffs' Trial Exhibit 13 for identification.

(Printout entitled "Practitioner Rx Transaction Record Edit Error Listing" (Cannizzaro 83-86), marked Plaintiffs' Trial Exhibit 13 for identification as of this date.)

MR. LESCH: I ask that there be marked a printout entitled "Schedule II Substances Dispensed and Processed in Month

of February" (Cannizzaro 83-86) as Plaintiffs' Trial Exhibit 14 for identification.

(Printout entitled "Schedule II Substances Dispensed and Processed in Month of February" (Cannizzaro 83-86), marked Plaintiffs' Trial Exhibit 14 for identification as of this date.)

MR. LESCH: I ask that there be marked a printout entitled "All Prescriptions Processed in Month of February" (Cannizzaro 83-86) as Plaintiffs' Trial Exhibit 15 for identification.

(Printout entitled "All Prescriptions Processed in Month of February" (Cannizzaro 83-86), marked Plaintiffs' Trial Exhibit 15 for identification as of this date.)

MR. LESCH: I ask that there be marked a printout entitled "Report of Duplicate Prescriptions Processed in Month of February" (Cannizzaro 83-86) as Plaintiffs' Trial Exhibit 16 for identification.

(Printout entitled "Report of Duplicate Prescriptions Processed in Month of February" (Cannizzaro 83-86), marked Plaintiffs' Trial Exhibit 16 for identification as of this date.)

MR. LESCH: I ask that there be marked a printout entitled "Unmatched

BNDD Numbers" (Cannizzaro 83-86)as Plaintiffs' Trial Exhibit 17 for identification.

(Printout entitled "Unmatched BNDD Numbers" (Cannizzaro 83-86), marked Plaintiffs' Trial Exhibit 17 for identification as of this date.)

MR. LESCH: I ask that there be marked a printout entitled "Patients With Rx Total Dose In Excess 30 Day Supply In Month of February" (Cannizzaro 83-86) as Plaintiffs' Trial Exhibit 18 for identification.

(Printout entitled "Patients With Rx Total Dose In Excess 30 Day Supply In Month of February" (Cannizzaro 83-86), marked Plaintiffs' Trial Exhibit 18 for identification as of this date.)

MR. LESCH: I ask that there be marked a printout entitled "Alphabetic Listing of Practitioner Master File" (Cannizzaro 83-86) as Plaintiffs' Trial Exhibit 19 for identification.

(Printout entitled "Alphabetic Listing of Practitioner Master File" (Cannizzaro 83-86), marked Plaintiffs' Trial Exhibit 19 for identification as of this date.)

MR. LESCH: I ask that there be marked a printout entitled "New York State Department of Health Physicians List By Name"

(Cannizzaro 83-86) as Plaintiffs' Trial Exhibit 20 for identification.

(Printout entitled "New York State Department of Health Physicians List By Name" (Cannizzaro 83-86), marked Plaintiffs' Trial Exhibit 20 for identification as of this date.)

MR. LESCH: I ask that there be marked a printout entitled "New York State Department of Health Master Mailing File" (Cannizzaro 83-86)as Plaintiffs' Trial Exhibit 21 for identification.

(Printout entitled "New York State Department of Health Master Mailing File" (Cannizzaro 83-86), marked Plaintiffs' Trial Exhibit 21 for identification as of this date.)

MR. LESCH: I ask that there be marked a letter to New York doctors from Commissioner Ingraham dated November 28, 1973 and attachment thereto (Baker 239) as Plaintiffs' Trial Exhibit 22 for identification.

(Letter to New York doctors from Commissioner Ingraham dated November 28, 1973 and attachment thereto (Baker 239), marked Plaintiffs' Trial Exhibit 22 for identification as of this date.)

MR. LESCH: I ask that there be marked a memorandum from Mr. Bellizzi to

Commissioner Whalen dated June 20, 1973 (Attachment 5 with letter dated July 12, 1974 from A. Seth Greenwald, Esq. to Michael Lesch, Esq.) as Plaintiffs' Trial Exhibit 23 for identification.

(Memorandum from Mr. Bellizzi to Commissioner Whalen dated June 20, 1973 (Attachment 5 with letter dated July 12, 1974 from A. Seth Greenwald, Esq. to Michael Lesch, Esq.), marked Plaintiffs' Trial Exhibit 23 for identification as of this date.)

MR. LESCH: I ask that there be marked a memorandum to Doctor Baker from Mr. McDermott dated October 11, 1973 (Deposition Exhibit 13) as Plaintiffs' Trial Exhibit 24 for identification.

(Memorandum to Doctor Baker from Mr. McDermott dated October 11, 1973 (Deposition Exhibit 13), marked Plaintiffs' Trial Exhibit 24 for identification as of this date.)

MR. LESCH: I ask that there be marked a memorandum to Doctor Baker from Mr. McDermott dated October 23, 1973 (Deposition Exhibit 9) as Plaintiffs' Trial Exhibit 25 for identification.

(Memorandum to Doctor Baker from Mr. McDermott dated October 23,

1973 (Deposition Exhibit 9), marked Plaintiffs' Trial Exhibit 25 for identification as of this date.)

MR. LESCH: I ask that there be marked an unsigned memorandum, dated June 12, 1974. Subject: Investigations going to more than one Doctor (1974) (Bellizzi 70) as Plaintiffs' Trial Exhibit 26 for identification.

(Unsigned memorandum, dated June 12, 1974. Subject: Investigations going to more than one Doctor (1974) (Bellizzi 70), marked Plaintiffs' Trial Exhibit 26 for identification as of this date.)

MR. LESCH: I ask that there be marked an unsigned memorandum, dated May 12, 1974. Subject: Case Reports of violations of going to more than one doctor, Cases Reported (1969-1974) (Bellizzi 45-46) as Plaintiffs' Trial Exhibit 27 for identification.

(Unsigned memorandum, dated May 12, 1974. Subject: Case Reports of violations of going to more than one doctor, Cases Reported (1969-1974) (Bellizzi 45-46), marked Plaintiffs' Trial Exhibit 27 for identification as of this date.)

MR. LESCH: I ask that there be marked a N. Y. State Department of Health Flier entitled "How the Controlled Substances

Act Affects Medical Practitioners in New York State" (Deposition Exhibit 21) as Plaintiffs' Trial Exhibit 28 for identification.

(N. Y. State Department of Health Flier entitled "How the Controlled Substances Act Affects Medical Practitioners in New York State" (Deposition Exhibit 21), marked Plaintiffs' Trial Exhibit 28 for identification as of this date.)

MR. LESCH: I ask that there be marked an audit report on Financial and Operating Practices, New York State Identification and Intelligence System, Report No. AL-ST-29-71 as Plaintiffs' Trial Exhibit 29 for identification.

(Audit Report on Financial and Operating Practices, New York State Identification and Intelligence System, Report No. AL-ST-29-71, marked Plaintiffs' Trial Exhibit 29 for identification as of this date.)

MR. LESCH: I ask that there be marked a stipulation among the Attorneys for the parties "So Ordered" on July 2, 1974 as Plaintiffs' Trial Exhibit 30 for identification.

(Stipulation among the Attorneys for the parties "So Ordered" on July 2, 1974, marked Plaintiffs' Trial Exhibit 30 for identification as of this date.)

MR. LESCH: I ask that there be marked a reporting of Sales of Dangerous Drugs, Second Interim Report of the Temporary State Commission to Evaluate the Drug Laws (Albany, N. Y. April 5, 1971) as Plaintiffs' Trial Exhibit 31 for identification.

(Reporting of Sales of Dangerous Drugs, Second Interim Report of the Temporary State Commission to Evaluate the Drug Laws (Albany, N. Y. April 5, 1971), marked Plaintiffs' Trial Exhibit 31 for identification as of this date.)

MR. LESCH: I ask that there be marked Proposed New York State Controlled Substances Act and Revision of the Penal Law, Interim Report of the Temporary State Commission to Evaluate the Drug Laws (State of New York - (1972) Legislative Document No. 10) as Plaintiffs' Trial Exhibit 32 for identification.

(Proposed New York State Controlled Substances Act and Revision of the Penal Law, Interim Report of the Temporary State Commission to Evaluate the Drug Laws (State of New York - (1972) Legislative Document No. 10), marked Plaintiffs' Trial Exhibit 32 for identification as of this date.)

MR. LESCH: I ask that there be marked a memorandum of Chester R. Hardt,

Chairman of the Temporary State Commission to Evaluate the Drug Laws (Appendix to Court of Appeals, pp. 40a-44a) as Plaintiffs' Trial Exhibit 33 for identification.

(Memorandum of Chester R. Hardt, Chairman of the Temporary State Commission to Evaluate the Drug Laws (Appendix to Court of Appeals, pp. 40a-44a), marked Plaintiffs' Trial Exhibit 33 for identification as of this date.)

MR. LESCH: I ask that there be marked plaintiffs' first set of interrogatories as Plaintiffs' Trial Exhibit 34 for identification.

(Plaintiffs' first set of interrogatories, marked Plaintiffs' Trial Exhibit 34 for identification as of this date.)

MR. LESCH: I ask that there be marked plaintiffs' second set of interrogatories as Plaintiffs' Trial Exhibit 35 for identification.

(Plaintiffs' second set of interrogatories, marked Plaintiffs' Trial Exhibit 35 for identification as of this date.)

MR. LESCH: I ask that there be marked defendant's responses to plaintiffs' interrogatories as Plaintiffs' Trial Exhibit 36

for identification.

(Defendant's responses to plaintiffs' interrogatories, marked Plaintiffs' Trial Exhibit 36 for identification as of this date.)

MR. LESCH: Let the record reflect that this deposition is being held pursuant to pretrial order No. 2 on consent made by Judge Carter on November 21, 1974, and in view of the fact that this is in lieu of trial, rather than an ordinary deposition, I am requesting that defendant's attorneys make all objections and reserve no objections for any future time.

In addition, I think the record should reflect that during the course of the trial before the three judge court on Monday, I made available to Mr. Greenwald a list of the actual names of the plaintiffs herein and their addresses.

Now unless anyone wants to say anything, I would like to commence the examination of Dr. Rosenberg.

MR. JAFFE: I would just like to add the one statement that I supplied the names of the co-plaintiff to Mr. Greenwald.

D R. J O S E P H M A R T I N R O S E N B E R G, called as a witness by the plaintiffs, being first duly sworn by the Notary Public (William Blitz), testified as follows:

EXAMINATION BY MR. LESCH:

Q Dr. Rosenberg, will you describe your background and qualifications?

A My name is Jerry M. Rosenberg and I'm presently head of the Department of Management and Professor of Management at Polytechnic Institute of New York in New York City.

Prior to that, I was from 1961 to 1964 an assistant professor of Psychology and Organizational Behavior at Cornell University.

From 1964 to 1968, I was an assistant professor at Columbia University, Teachers College.

From 1968 to 1971, I was in private practice.

From 1971 until this past summer, I was an associate professor at Baruch College, City University of New York and teaching in the Department of Psychology.

Q What is your formal education, sir?

A I received a Bachelor of Science from the

City College of New York, with a major in Psychology in 1956.

Master's degree was awarded in 1957 from Ohio State University in Psychology.

As a recipient of a Fulbright and French Government Award, I attended in 1958 the Sorbonne University of Paris at the Center of Higher Studies for which I was awarded a certificate, and completed my Ph.D. 1962 at New York University.

Q Have you written any books or articles in the area of privacy?

A Yes, I have.

I've written a book which was published in 1969 by Random House with the title, "The Death of Privacy, Do Government and Industrial Computers Threaten Our Personal Freedon?"

The book, by the way, was selected by The New York Times as one of the best books of interest in the year 1969, one of the 22 best books of the year, and following that there have been numerous occasions speaking across the country before industrial groups, colleges, lectures, writings, etc.

Febraury, 1971, I was called upon by Senator Irvin to testify on opening day at Constitutional

Rights Subcommittee hearing on federal data banks, privacy and the Bill of Rights. I did testify. The results were printed in the U. S. Congressional Record, and also appeared in the federal publication of the senate hearings.

I might just add that I continue to be active in the field, research and writing on the subject.

Q Dr. Rosenberg, would you describe your other writings in the areas of computers and privacy?

A I've had two other books which were published also in the year 1969, a book called "The Computer Prophets" published by Macmillan, which dealt with the historical evolution of the computer. Inserts within that book deal with the issue of privacy also.

Another book on -- called "Automation, Manpower and Education" published 1967 by Random House dealt with many of the technological aspects, change, and issues of submission of man. Some of the psychological concerns are also part of that.

Some of the articles on privacy without giving specific titles, since I don't have them in front of me --

Q May I show this to you to refresh your recollection.

A A paper 1962 which was a position paper

prepared for the Union of American Hebrew Congregations convention in Los Angeles titled "Surveillance and Privacy."

MR. FOGARTY: May we have an identification of what he is reading from.

MR. LESCH: Sure.

Dr. Rosenberg is reading from a list of his publications which he previously provided me.

THE WITNESS: 1971, a speech given at Wesleyan College in Macon, Georgia titled "The College Student and Freedom."

1971, March 24th, "Students Rights" a paper delivered at North Dakota State University in Fargo, North Dakota.

The 25th of March, 1971, "The Death of Privacy" a paper presented at the College of St. Mary, Omaha, Nebraska.

May 19, 1971, convocation address at the State University of New York at Oswego, New York titled "The Right of All Men to Privacy."

A paper delivered on August 19, 1971 before The Council of State Governments

National Convention in Minneapolis, Minnesota titled "The Government's Responsibility to Protect the People's Right to Privacy."

November 9, 1971 before the Canadian Information Processing Society in Toronto entitled "The Threat to Individual Freedom."

February 9, 1972, LaSell Junior College in Auburndale, Massachusetts, "Student's Rights on a Changing Campus," the topic of the paper.

April 13, 1972, High Point College in High Point, North Carolina, a paper presented entitled "Campus Surveillance."

May 8, 1972 at Muskingum College in New Concord, Ohio, "The Right of All Men to Privacy."

May 25, 1972, at Southern Illinois University, Carbondale, Illinois, delivery of the convocation address entitled "The Age of Aquarius versus The Age of Aquariums."

September 28, 1972 at Plymouth State College, Plymouth, New Hampshire, entitled

"Student's Rights and Psychological Submission."

And a presentation on November 6, 1973 at St. Lawrence University in Canton, New York entitled "Watergate - Implications for Student's Rights."

BY MR. LESCH:

Q Are you familiar with Article 33 of the Public Health Law of New York?

A Yes, I am.

Q Have you at my request made a study of the behavior or psychological affects of the accumulation of the personal data called for by Article 33 on the privacy of the individuals affected?

A Yes, I have.

Q What are the psychological or behavioral affects of the filing requirements of Article 33 of the New York Public Health Laws and particularly those provisions requiring the filing of copies of prescriptions for Schedule II drugs?

A I understand that each month approximately 100,000 records are stored in Albany relating to triplicate forms of users of Schedule II drugs, and I claim that within this 100,000 population certainly a sizeable percentage will have some chilling affect or psychologi-

cal impact resulting from the documentation data.

Q Can you be more specific and give us the areas of psychological or behavioralreactions that will occur when there is an awareness of an individual that his personal data is being recorded?

A I think there are a number of very important areas. Just to identify them, I think it could lead to conformity by the individual, it can lead to withdrawal, loss of autonomy, failure to express truthful statements, decline in productivity, a cold personality, "cold personality" may evolve, physical symptoms may appear, and others.

Q Sir, what do you mean when you say that a pattern of conformity may develop?

A I start off first by saying to some extent everyone conforms, every human being conforms to the pressures from the outside.

In this particular case, I think that people who have some reason to be captious or are fearful of reprisal will tend to adjust their behavior and thinking to what they believe is corrected or anticipated behavior.

Let me give you an example here.

I think people who are outspoken, when

they feel that there is a record kept on them in some agency, particular government agency, because of fear of reprisal, they may not feel free or willing to express openly their feeling of antagonism, mistrust or just general attitude toward government, as I said, because of some fear that it may affect them in the long range because of it being documented and misused by the agency. The same would apply in an industrial setting, too.

Once there is a knowledge that information is recorded, for some people it will have a psychological caution, a button will be pressed to be a little more careful as to what you are saying.

Q Dr. Rosenberg, in the area of the filing of triplicate prescriptions, would the knowledge by an individual that prescriptions containing his name and the drug that he is taking have an affect on that individual's behavior with respect to taking the drug?

A May very well.

Q What type of affect would it have?

A As in the previous example, knowing that information is being recorded, that may raise a number of questions within the individual. How is it used, how is it misused, who has access to it.

Even statements saying that it will be

destroyed, a person may question whether there is truth behind that statement. And so again the conformity issue is raised out of fear.

Q Is there a likelihood that such persons will tend not to use the drug as was the case, for example, with Mrs. Poe, I believe, one of the witnesses who testified in this case on Monday?

A Yes.

Q You also mentioned a pattern of withdrawal, Dr. Rosenberg. What did you mean by that?

A By withdrawal, I mean that people will impart or totally remove themselves from an active role in society when threatened, and I think there are numerous examples here. Let me cite one.

A case in 1970, when the United States Government was participating in the national census, they found that in the urban centers where there were large numbers of welfare recipients that they were unable to have access into their homes, many of their homes, and one of the major reasons that the recipients were unwilling to allow the census takers to come in was because of a refusal to allow them to see what their private world was all about.

In other words, people do withdraw and

wish to and demand a world away from the eyes of big brother or the government.

Q How would this pattern of withdrawal manifest itself in the case of an individual about whom triplicate prescription data is filed in Albany?

A Well, again the analogy, I think, is appropriate in that a number of such people may withdraw psychologically. They may actually withdraw from taking the drug, because they refuse to have the record put on tape in a computer in Albany.

They may withdraw in other ways. The fear may create resistance to sharing themselves with other people and they may just withdraw inwardly.

Some psychiatrists have done very extensive studies on this. I'd just like to cite a very critical study by the eminent Dr. Horney who showed in her research that people who are continuously concerned about their privacy being intruded upon, a reaction can be a total withdrawal from society, carrying the pendulum to the other extreme and threatening withdrawing completely.

Q You also mentioned a decline in productivity, Dr. Rosenberg. What did you mean by that?

A People who are threatened or in fear of information being recorded or people who lose their

privacy react to this by their productivity or active role on the job by being affected in a negative sense. A number of studies to support this.

During the second World War, Dr. Maslow, M-a-s-l-o-w, who was a former president of the American Psychological Association, showed that prisoners, prisoners in camp, concentration camps, were derived of many of their physical and psychological needs, one of them being lack of privacy where they were constantly being observed by guards and more importantly by fellow prisoners, and because of this lack of seclusion, they were unable to perform their activities openly and with success.

There are other examples. Dr. Katzell, K-a-t-z-e-l-l, Professor of Psychology at New York University, conducted a study in which he showed sailors on board submarines also lacked a private world. It's very hard to hide in a submarine away from other sailors. This led to increased hostility and mutual mistrust.

Q What is the bearing of these studies, Dr. Rosenberg, on the filing of the triplicate prescription form in our case?

A Well, I think there could be two direct links here.

No. 1, that the information or the perception that information may be recorded can affect the child's performance in school, socially, sports, etc.

And I think also, another direct link, is that fear increases a mistrust, and here we would be very concerned with the relationship between the patient and the doctor. If indeed the doctor is perceived by some patients as an agent -- in quote -- an agent of the state, and might reveal some of this data because he is obligated to reveal the data to an agency, this inevitably must affect the relationship between the patient and the doctor.

Q Are you saying that it will affect the relationship because the patient will be less frank and forthcoming with the doctor?

A Yes.

Q You also mentioned creating a warm or a cold personality. Will you explain what you meant by that?

A Well, I put these two words in parenthesis because they are subjective words.

Q You mean quotation marks?

A What did I say?

Q Parenthesis.

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A Quotation marks. Thank you.

That the way the individual reacts to his society can definitely affect his attitudes and the way in which his personality will evolve.

Let me give you two very critical studies here. A gentleman by the name of Spiro, S-p-i-r-o, who was a leading researcher made a study of the Israeli kibbutz, and he found that children who grew up 25 years ago on a kibbutz were very antagonistic toward their style of life which limited the amount of privacy that they had as they were growing up on a kibbutz, sharing rooms, sharing a room with many children, and the overwhelming reaction to this is that the next generation of Israelis to a very great extent refuse to permit their children to share the kibbutz life, with the major reason being the lack of privacy.

I think a more important study made by a gentleman named Gertz, G-e-r-tz, who did anthropological study in Indonesia. He compared two societies, the society of Java and Bali. To a great extent these two societies are very similar.

One very important difference relates to the issue of privacy. The people in Bali have what are referred to by Gertz as warm personalities. They are

open, they are free in their communications, while in Java, they are very stuffy, very cold. And he attributes this to the style of life that they had as they were growing up and interacting with other people.

In Java, there is virtually no privacy in their society. Huts are designed which do not have doors. There are no walls in their society. One cannot easily hide from observation. People are constantly walking in and out of rooms. One dresses and undresses with people around.

And he compared this to Bali where there are stone walls around huts, where there are doors, where there is seclusion.

And his linkage here is that those from Bali who have the privacy evolved and had warm personalities, while in Java since they had limited or no privacy reacted by becoming very cold and stuffy in their personality.

Q What is the affect of this type of observation that you have been making with respect to the triplicate prescription law that is at issue in this case?

A Again, I draw a direct line here saying people who are fearful of loss of privacy may evolve and

certainly some will evolve having a rather cold, stuffy personality, and not passing a negative judgment on this, I think the critical question what kind of society do we want. Do we want people to be open and free or do we want them to be cold, suspicious.

Q You also mentioned a loss of openness or smaller likelihood of truthful expression. What did you mean by that?

A I think a critical point in revealing what is -- what one believes in very often it can only be done comfortably when one is secluded from the outside world, and when one does not have this opportunity, one will refrain from revealing truthful statements.

I think there are numerous examples of this. Major decisions by corporations are not made before the open camera very often. They are made in a closed board room.

Critical decisions in labor management negotiations likewise, may take place in a private smoke filled room with few people there.

Judges chambers are used for decisions that are made without access by the public.

It is interesting to note that when the Constitution of the United States was framed in

Philadelphia, it was done in a closed meeting where no outsiders were permitted other than those who were needed, and every participant in the drafting of the Constitution was sworn to secrecy.

Q And closed sessions of congressional committees would be another example.

A Yes, it would be.

Q What is the conclusion that you derive from these various mechanisms of society that are established so as to insure confidentiality while deliberations are being made?

A Excuse me. I didn't --

Q What is the conclusion that you draw from these various mechanisms that you have described that are designed to insure privacy and confidentiality while decisions are being made?

A What mechanisms?

MR. LESCH: Would you read beack the question?

(Read question.)

THE WITNESS: I conclude that there are various negative strains put upon people and fears created because of this collection of information on a computer in Albany.

Q And that persons are likely to be more truthful and freer in the expression of their ideas, if they are not threatened by one invasion of their privacy or another?

A Right. Absolutely.

Q How would that bear on the required filing of triplicate prescriptions under the statutes that we're discussing?

A Well, truthfulness requires a feeling of comfort, security, and if people or patients are concerned that this information is recorded, they will be less truthful with their doctors and the doctors may be less truthful with the patient.

Q Would that also apply to a legislator about whom a triplicate prescription form was filed?

A It might very well be so.

Q You also mentioned, I believe, a loss of autonomy. What did you mean by that?

A Well, by loss of autonomy is meant that people should decide for themselves when they want to go public, when their private world is to be revealed, and it should not be decided by an outside organization.

I think an example which is very pertinent here is that the United States Army has a set of records

released upon a soldier's leaving the military. These records contain a host of information which includes coded symbols which might indicate some behavior on the part of the soldier. And this is used or perceived -- excuse me -- this is perceived by the soldier as a form of control or coercement.

Q Are you saying that the Army uses the threat that unfavorable information will be revealed about a particular soldier or about all of the soldiers in the Army as a method of controlling them while they are in the Army?

MR. FOGARTY: Objection.

A It could be used.

Q What is the bearing of this loss of autonomy as you have described it on the triplicate prescription law that we're discussing here?

A That information so recorded might be used in a -- might be used to coerce or force people into certain behavior patterns, might. I emphasize the word "might."

Q You also mentioned that there are physical symbols that can result from invasion of an individual's privacy. What did you have in mind there?

A All people physically react to excessive

strain. In this particular case, when there is -- when the individual sees pertinence in the information being released, if he thinks it is very critical to his destiny, he may react physically by sweating, by exhaustion, by blood clotting.

There are some very important medical studies that have been made in this area. Several cardiologists in San Francisco a few years ago found that certified public accountants when they work -- who work on income tax develop as a result of a strain over a four month period increased blood clots, and this peaks on April 15th of the year.

Recently, there have been statements made by physicians, psychiatrists, regarding President Nixon, former President Nixon's phlebitis and illness which has been directly connected to blood clotting. And they state that the increased disclosure, forced disclosure has put a heavy burden, heavy pressure on the former President which has led to these physical symtoms.

Q Dr. Rosenberg, what is your conclusion? Specifically is there a negative psychological impact on every person who knows that a triplicate prescription concerning drugs that he or his family is taking are filed in Albany?

A There is a negative impact, yes.

Q Are you saying that in certain cases this negative impact will be substantial and will result in one or more of the psychological and/or behavioral reactions that you have just described?

A In certain cases, yes.

MR. LESCH: I have no further questions.

The record should reflect that during the course of Dr. Rosenberg's examination, Mr. Ambrose Donovan, who is an attorney for the Department of Health, and Mr. Joseph Cannizzaro entered the deposition room.

(Short recess.)

EXAMINATION BY MR. JAFFE:

Q Dr. Rosenberg, in your study of privacy, have you found that there are particular areas of human conduct in which individuals and society expect privacy?

A Yes, I think most people expect a degree of privacy in their daily life. Certainly we expect privacy in sexual relations. We expect privacy in conversation with close friends. We expect privacy in relationships with medical persons, psychiatrists, psychotherapists. There are other relationships

certainly.

Q But the expectation with doctor is a traditional and well established expectation?

A I think it's called privileged communication.

Q That is not only expected in effect by the individual, but it is an expectation which society has generally accepted, is that correct?

A Right.

Q You have described a series of damaging effects which are the result of a loss of privacy. Would those damaging effects be increased, if the situation in which they took place was already a stressful situation?

A Yes.

Our behavior and thinking process is very much influenced by what we expect, what we anticipate, how we perceive a certain environment.

If this -- even before this information is recorded on a computer in Albany, even prior to a patient knowing about this, any situation which might be a reversal of what the patients anticipates --

Q Dr. Rosenberg, I am speaking about the facts that, for example, some of the examples you used were concentration examples -- that's an extreme example.

A Right.

Q But in this litigation we're involved in the taking of a serious drug which is in itself a situation of strain.

A Right.

Q That situation could be a situation in which the patient is seriously ill, for example.

In the situation where the patient is seriously ill, would not the likelihood or the degree of damage from the conditions you have described be increased?

A Yes, it would be. It might be. There might be an increased strain.

Q In that situation, you have already said the patient would expect privacy. Is it not true that the discovery on the patient's part when under a condition of strain that his conduct was about to be recorded would create an increased strain at that point?

A It might very well increase the strain, yes.

Q Isn't it true that not only would there be a resentment on the part of the patient that his privacy was going to be denied, but also that his expectation had been radically reversed?

A Yes.

Q That would increase his sense of strain?

A Any reversal or alteration of expectancy would increase frustration, expectation or strain, yes.

Q Would that have any impact on his feeling of loss of privacy?

A Yes, it would.

Q Would this law as you understand it as a result increase the damaging affects which you have described to the patient?

Let me rephrase the question.

Would the existence of this law have increasing damaging affects on the patient?

A Yes, it would.

MR. JAFFE: I have no further questions.

EXAMINATION BY MR. FOGARTY:

Q Mr. Rosenberg, I think your basic thesis initially was that fear begets conformity.

A A major thesis, yes.

Q Where in your opinion would fear come from with regard to Schedule II drugs?

A It comes from within the person. It's a judgment made by the individual.

Q But it would have to be based on something outside the individual, would it not?

A Yes, it would be.

Q Where do you think that would come from?

A In terms of Schedule II drugs?

Q That's right. We're only talking about Schedule II at this moment.

A It would come from knowledge that such records are kept, and a concern for how confidential these records would be, who has access to them, who might have access to them when the person has no authorization for access, how long will these records be maintained.

Fear might come from the concern that others who would be in a position to control his life, employers, teachers, other people in positions of power, who might have -- gain access to this information and perhaps use it against him.

Fear is a very subjective term and much of the fear is real and part of the fear, of course, is created, but the created fear which may be fictional still plays a very powerful role in the individual's psyche.

Q So that, in effect, Mr. Rosenberg, fears are based really on what we found out or what people tell us, plus our experience, but at this point we will

talk only about what we know or what people tell us.

A I agree. A good part of the fear is based on experience and what people tell us, but there is also a good part of the fear is what we think will occur.

Q No question of it.

Would it be fair to say that the normal person's fear decreases as his knowledge increases?

MR. LESCH: Knowledge of what? If it is knowledge of something fearsome, I suppose the normal person's fear would increase.

MR. FOGARTY: Are you making an objection, Mr. Lesch, or a comment?

MR. LESCH: I am objecting to the form of the question.

MR. FOGARTY: Fine.

Answer the question, please.

THE WITNESS: Would you repeat the question for me.

MR. LESCH: If you don't understand the question, you don't have to answer it.

MR. FOGARTY: Would you like to testify, Mr. Lesch?

MR. JAFFE: There is an objection.

MR. FOGARTY: The last thing was

not an objection. It was a comment to the witness.

MR. LESCH: I was instructing the witness that he does not have to answer a question, if he can't understand it, and that he has the right to ask you, Mr. Fogarty, for clarification of any question that he does not understand.

MR. FOGARTY: But he hasn't asked me for it yet, has he?

MR. LESCH: There was a puzzled expression on his face which precipitated my remark to him.

MR. FOGARTY: Would you repeat the question to the witness, please.

(Read question.)

A Would you explain what you mean by knowledge?

Q In this case we're limited to Schedule II drugs.

A You're asking would his fear increase as --

Q Would his fear decrease?

A Would his fear decrease as he learns that there is a recording being made of his usage of Schedule

II --

Q That basically I think we would have to assume he knows, that that's part of the basis of his fear.

A The answer is it may increase.

Q If the --

MR. LESCH: Did you say increase then?

THE WITNESS: It may increase. The fear may increase.

Q If the patient learns exactly what information is being transmitted to the Department of Health who are the custodians of Schedule II prescriptions, do you think that might affect his fear?

A I'd like to ask -- when we're saying the person, are we talking of the child as the person, are we talking of the parent of the child? Because I think there might be different answers based upon who is the person.

Q Basically you are going to be talking about adult people because I don't think that doctors are going to discuss Schedule II drugs with a child. They will be discussing them with the parents and not with the child. At least I would assume that to be the case. That has been the testimony so far.

MR. LESCH: It seems to me, with all respect, Mr. Fogarty -- are you making the assumption that a child will not find out about the fact that triplicate prescriptions are being filed merely because the doctor does not tell him that?

MR. FOGARTY: I am talking about the imparting of knowledge. I am not talking about what the child knows. At this particular point that's what I'm talking about.

MR. FERZIGER: I am going to object to the question as to form.

MR. FOGARTY: Would you answer the question, please.

A The question -- might you read the question.

(Read question.)

MR. FERZIGER: I have an objection to the question as to form.

A First let me say I haven't -- I do not know exactly what the questions or items on the form are. So I cannot give a total answer to your question.

It indeed might minimize the fear, if he knows what the questions are. It might minimize the fear. However, I don't think it is alone an issue of

what information is being collected. I think it's a question of how the information would be used or misused.

Q Do you think that if there was imparted to a patient or the parent of a patient the purpose for which the information was being transmitted that this might have an affect on their reaction or their fear?

A It might have an affect. It might have an affect.

Q Would you agree, Mr. Rosenberg, that what we are dealing with in Schedule II --

MR. LESCH: This is Dr. Rosenberg, by the way.

MR. FOGARTY: I'm sorry. I usually use that with reference to medical people, but my apologies, Doctor.

Q -- that the substances in Schedule II are dangerous substances?

A The general definition of the word dangerous, I would agree.

Q And that they are so regarded by the medical profession as well as the legislator?

MR. FERZIGER: That is objected to.

MR. LESCH: I object to this question. Dr. Rosenberg is not a member of

the medical profession. He is not qualified to answer this question.

MR. JAFFE: I object in substance. I don't believe they are nor is there any showing that they are dangerous.

MR. FERZIGER: I further object to the question on the grounds that the legislator has not deemed them to be dangerous drugs.

Q Dr. Rosenberg, you stated you are not aware of what goes into a Schedule II prescription.

A I have not seen a Schedule II prescription form.

Q But you are familiar with Article 33?

A Yes.

Q You have no knowledge of what is reported to Albany?

A I don't have total knowledge of what is -- I don't have total knowledge of all the information requested.

Q What is your knowledge of what is reported to Albany or your understanding?

A Patient's name address, some biographical -- that includes some biographical information, and information about the drug itself.

Q What type of biographical information?

A I believe it would include his age, certainly the doctor's name might be -- I don't know beyond that what else would be included.

Q What information about the drug would be placed in it?

A I don't know the specifics on that.

Q What type of information, Doctor, goes into a normal prescription, other than Schedule II?

MR. FERZIGER: I am going to object to that on the grounds that he is not qualified as a physician.

A I can answer that as an ordinary citizen who has had prescriptions.

Q Fine. I will ask another question.

Have you ever been to a doctor?

A Medical doctor?

Q Yes.

A Yes.

Q Have you ever had a prescription?

A Yes.

Q Do you recall what kind of information was on it?

A If I could read it, I think I would

conclude it would have in addition to the doctor's name imprinted on the prescription, patient's name, my name in this case, the drug or medicine requested, the amount requested. I don't know. There might be other things. I've never studied prescriptions.

If I knew they were being recorded in a computer, I might study them more carefully.

Q If you were aware that the State Department of Health had access to them whether they were in the computer or not, would you have studied them?

A Yes.

Q Were you aware that they have always had access to them?

A To all prescriptions?

Q Yes.

A No, I was not aware.

Q You were not aware that under the law the Department of Health could at any time go into a pharmacist and examine all the prescriptions in his possession?

A No, I was not aware.

Q Does it change your opinions now that you are aware of it?

MR. LESCH: Opinions of what?

MR. FOGARTY: Opinions expressed here today.

MR. LESCH: He was not expressing any opinions with respect to ordinary prescriptions. Therefore, I object to the form of the question as misleading.

MR. FOGARTY: Would you answer the question, Doctor, please.

MR. LESCH: If you are able to answer the question.

A You want to know if it changed my opinion?

Q Yes.

A No, it does not change my opinion.

Q It does not change your opinion as to privacy or anything else?

A Now I don't understand the original question.

Q The question was that the regular prescriptions are as available to the State Department of Health as the Schedule II.

MR. FERZIGER: That's objected to as to form and content in view of the fact that it is not the situation. The situation in the old 33 was that the pharmacist must have kept a record and if the Department wanted

to make an investigation, they could go in and ask the individual pharmacist to look at his records.

MR. FOGARTY: Fine, Mr. Ferziger. That made them available to the Department of Health, did it not?

MR. FERZIGER: Only on an investigation.

MR. FOGARTY: That made them available, did it not?

MR. FERZIGER: No, it did not in my opinion.

MR. FOGARTY: That's your opinion. Would you answer the question.

MR. JAFFE: There is an objection to the question.

MR. FOGARTY: There is an objection and it is on the record. Answer the question. The judges will rule.

MR. FERZIGER: He is directed not to answer.

MR. LESCH: No, wait. Let him answer. If the witness is able to answer the question, let him answer.

MR. FOGARTY: Fine. Exactly, Mr. Lesch. The judges are going to pass on these objections, not us.

A I have to get clarification of what your question is. I would like it repeated by you or the reporter.

MR. FOGARTY: Read the question.

(Read question.)

MR. LESCH: Off the record.

(Discussion off the record.)

MR. FOGARTY: Would you read the original question to the witness, please.

(Read question.)

THE WITNESS: The question is does it change my opinion.

MR. FOGARTY: Yes.

THE WITNESS: Substantially, it does not change my opinion.

I would just make this one point. In my judgment as an individual, there is a big difference between information recorded in a computer in Albany and the right of the State to seek a prescription from a pharmacist. There is a big difference there.

BY MR. FOGARTY:

Q What do you see as the big difference, Doctor?

A One is when it's computed -- when it's within a computer, it's easily retrieved by a mere press of a button. Information is physically available.

The other takes effort, time, manpower, forms have to be filled out, I imagine, to request the information from a pharmacist.

Q But nothing would have to be done to get it out of the computer, is that your thesis?

MR. LESCH: I object to the form of this question again. He said that a button would have to be pressed.

Q Is that all that would have to be done to a computer?

MR. LESCH: The same objection.

A I'm not a computer expert.

Q You have expressed an opinion as to what has to be done, Doctor. That's why I am asking you.

MR. LESCH: He has just answered that he is not an expert and he is unable to answer your question.

MR. FOGARTY: He did not say he

was unable to answer it. He said he was not an expert.

A Request for authorization, demand certain forms and approvals be made. So it's not just the -- anybody pressing a button.

Q Are you aware of any of the procedures involved in obtaining information about Schedule II prescriptions?

A Specifically Schedule II, no. I have an awareness of regulations regarding access to computers in government agencies.

Q Are you aware of the regulations regarding access to computers by the State Department of Health?

A I have knowledge of access to government computers in the State, not specifically --

Q Would you answer the question, please.

MR. LESCH: He is answering the question.

A I did. I just did. I was cutoff before I finished my sentence.

I did not have any specific knowledge of public health agency.

Q The State Department of Health?

A Yes, the State Department of Health.

Q Are you aware of the confidentiality provisions of the statute involved here?

A Regarding Article 33 regarding --

Q The statute we're involved with in this proceeding.

A In the Public Health?

Q That is right.

A I have heard about the confidentiality aspects of it. I have never seen it or read it.

Q From whom did you hear about it?

A Mr. Lesch and perhaps others.

I may have passed it in reading some -- some materials.

Q Do you think it would have an impact on the people working with this information who are charged with the confidentiality of it--

A Impact?

MR. LESCH: May we have that question read back, please.

MR. FOGARTY: I have not finished it yet.

MR. LESCH: Excuse me. You ended with a raised voice so I assumed you finished the question.

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MR. FOGARTY: It will be raised a lot more before we're through.

Incidentally, what I would like to get straight now is that the objections come through you, not objections coming from other counsel.

MR. LESCH: I represent the plaintiffs, Roe, et al. I am making objections for them. I don't represent the Patient, et al., so that I suggest that Mr. Jaffe and I make objections.

MR. FOGARTY: I am only suggesting it so we get through.

MR. LESCH: What you are saying is agreeable to me as stated before.

MR. FOGARTY: Is it agreeable to them? This is what I don't know.

MR. JAFFE: Are you talking about me at this point?

MR. FOGARTY: Both of you.

MR. LESCH: What I said is I can only object on behalf of the plaintiffs that I represent, but I can't object on behalf of plaintiff, Patient, et al., because I don't

represent them.

MR. FOGARTY: In plain English you refuse then.

MR. LESCH: Off the record.

(Discussion off the record.)

BY MR. FOGARTY:

Q Do you feel that the confidentiality requirements of the law imposes an obligation on the people handling this information to respect that confidentiality?

MR. LESCH: Objection.

A Are you talking of government employees?

Q Yes.

A State government employees?

Q I am inclined to think I'm talking about more than that because more than State government employees handle Schedule II prescriptions.

MR. LESCH: What the witness is asking, Mr. Fogarty, is that you make clear to him who you are talking about in the question. Moreover, you are asking him for interpretation of the State law. I really don't see --

MR. FOGARTY: I am asking for

his opinion not of the State law.

MR. LESCH: You are asking him for his opinon as to what obligations are created by the confidentiality provisions of Article 33 and that's the reason I object to the question.

MR. FOGARTY: He is an alleged expert on privacy.

MR. LESCH: He is not an alleged expert in interpretation of statutes.

MR. FOGARTY: He has interpreted enough of them on direct examination to tell us about them.

MR. LESCH: I beg to differ with you. He has not interpreted any on direct examination.

Q Let's start with the doctors and go right through the State employees, Doctor. That includes the pharmacist who fills it.

Do you think that the statute in imposing confidentiality has an impact on these people?

MR. LESCH: May I ask that in all fairness he be shown a copy of the statute which he is now being asked to interpret.

MR. FOGARTY: He testified on direct he is familiar with it.

MR. GREENWALD: Off the record.

(Discussion off the record.)

MR. FOGARTY: Read the last question.

(Read question.)

MR. LESCH: Let the record reflect that we have handed Dr. Rosenberg a copy of the Article 33 of the Public Health Law and I have directed his attention to Section 3371 thereof, which I understand to be the provisions to which Mr. Fogarty is referring. If it would help speed this up, Mr. Fogarty, I would be willing to stipulate that the statute applies to persons who have knowledge by virtue of their office of the contents of the triplicate prescription forms among other documents.

MR. FOGARTY: Fine. I will accept the stipulation. Then I would like the doctor's answer.

A I would first like to say as it has been stated before that I am not a legal expert nor a medical

physician and follow that by saying there is a difference in doctors and physicians and State employees having access to information.

Pharmacists and doctors, of course, have to be licensed by the State, and confidentiality is a very important and sensitive issue to them and I think that their behavior would and should be controlled.

I also -- with employees, bureaucratic employee, they are not licensed or certified by the State as far as I know. And I think even though they are very sensitive to the issue of confidentiality, there have been repeated breakdowns in this adherence to the regulations. And I think any book on the issue of -- any scholarly critical book on data accumulation will show that overzealous bureaucrats have at times entered files when they should not have.

Q What are overzealous bureaucrats, Doctor?

A It's a phrase used by a great number of people to describe employees of a government agency who in their dedication to their task, in their eagerness to do a thorough job might go a little too far. I think that is what is meant by overzealous.

Q Would you define the second part of your term?

A Bureaucrat?

Q Yes.

A A bureaucrat, I would define -- and I'm not sure this is the definition within a dictionary, but I would define it as a bureaucrat is any person who works for a government agency.

Q Would your definition change any if that employee was a doctor?

A A doctor employed by the State?

Q Yes.

A He is a doctor and a bureaucrat also.

Q His status changes, I assume, from your comments.

A His status?

Q His respect for confidentiality, let's say, changes when he becomes a state employee.

A He is still licensed as a doctor by the State and his foremost --

Q In other words, he has just as much respect for confidentiality as a private practitioner, does he not?

MR. LESCH: I object to these questions on the grounds that they call for speculation about unnamed doctors and unnamed physicians, and they are entirely, with all

respect, meaningless.

Q Dr. Rosenberg, you said pharmacists have a very high regrad for confidentiality, right?

A No, I didn't say that.

Q You said that doctors --

A And pharmacists who are licensed by the State should have a greater respect.

Q But you didn't say should, did you?

MR. LESCH: Now we're arguing with the witness. The record says what it says, Mr. Fogarty.

A I can't take all doctors and pharmacists in the State and say they do have. I don't -- I have never interviewed them.

Q Thank you.

The examples you gave us of stress situations and people's reactions or fear of information becoming or getting outside themselves, if we can put it that way, are all regarding people in confined environments, aren't they?

A Confined?

Q You talked of the Army, submarines, the kibbutz. All of these people are in what might be considered a confined environment?

A In the examples you just threw back were in some respects confining, but there were examples given that were not in confined environments.

Q What examples did you give that were not confined?

A I gave an example of certain public accountants. I gave an example of the President of the United States. I gave an example of, I think, children and peer pressure within a classroom. Speaking out in terms of expressing one's point of view about government or industry.

These are not confining.

When you say confined, I think of walls, confining a person.

There are examples in that category and there are examples not in that category.

Q Did you give any examples dealing with State laws regarding prescriptions?

A Did I give any examples?

Q Yes.

A No, I did not give direct examples.

Q Have any studies been made?

A Of what?

Q Of laws similar to this.

A Have any studies been made of laws?

Q Of the affect of laws similar to this on people.

A Well, if you say studies, you mean published studies?

Q I am talking generally of the examples you gave which were the product of studies made by, I would assume, colleagues in either the medical or psychological fields.

A There might have been some studies.

Q But you are not aware of them, are you?

A Specific to --

Q This particular problem.

A With this specific problem?

Q Right.

A No, I am unaware of it, of any such studies.

Q So that --

A The statute went into effect a year and a half ago approximately, right?

Q That is correct, in New York.

A So I would -- it would be very hard to find any such studies made in the past year and a half, if indeed any such studies were made.

Q Would it be hard to find studies in the

last 20 years in California?

A I don't know.

Q You spoke about submarines, you spoke about the Army. They are not all in New York. California has had a statute similar to this for 20 years.

A So you are asking if any such studies have been made in California?

Q If you are aware of any such studies.

A No, I'm not aware.

Q So that your application of the studies is in a sense hypothetical?

A Is in a sense hypothetical?

Q Right.

A I'm drawing from these studies to conclude something.

If your question is do I have direct evidence from Schedule II drugs in a study made of Schedule II drugs in New York State, the answer is no.

Q Fine. That precludes my next question.

A I'd like to add something which I think we're overlooking. Maybe it's in a future question.

But the major thrust in my statements does not deal with the data in a computer in Albany and how it may or may not be misused, although that

is a critical problem and concern.

I am building an argument that just the accumulation of data has a negative affect upon people. And also I am saying that people are not secure in knowing how this information is handled. You may show all sorts of precautions against leakage, against intrusion. I'm saying that the public does not have faith because there have been enough examples where there have been intrusions that this in and of itself, what they think, will create a number of fears and strains on their individual well-being.

Q This, of course, is your opinion of what they think?

A Is my opinion based on studying the area, studying the issue.

Q On the studies that have been done that you have related to us?

A No, far beyond that. Studies done of information collected on people and put in storage. There have been studies made.

Q But you have related the effect of those studies to us, haven't you? On your direct examination you went over them, didn't you?

A I left out some studies which also support

that people are very cautious, antagonistic, not trusting.

I understand Monday -- I was not at the hearing Monday. I understand there was a man who was -- who is dying of cancer -- excuse me.

Q I am listening to you. Don't try to analyze me at this short range.

A I'm not trying to analyze you. I thought you were trying to cut me off.

Q No. Don't worry. When I want to cut you off, I will cut you off and you will know it. You were going to say something, Doctor. If you want to say it, go ahead.

MR. LESCH: You started to say a man was dying of cancer.

THE WITNESS: A man was dying of cancer who needed a certain drug which is under Scheudle II and went out of his way to go to New Jersey to get this drug -- I don't know how often he would have to go, but he went out of his way to get the drug in New Jersey so as to -- so it would not be filed because of regulations not required in the State of New Jersey.

Now this takes effort, gumption,

perseverance. It reflects an attitude.

Q Was it also related to you, Doctor, that that attitude was based on lack of information?

A Lack of information?

Q Yes.

MR. JAFFE: Objection.

It is simply not true.

A I don't understand what you mean.

Q Was it also related to you that on cross-examination the man pointed out that he made claims to an insurance company for those prescription drugs?

A No, that was not mentioned.

Q So that he was placing the information into other computer, wasn't he?

MR. JAFFE: Objection.

A I don't know enough to answer or respond.

Q I see. You only know what you were told.

A But the point I'm making today --

Q I know the point you are making, Doctor. That is the end of my question.

MR. LESCH: Do you want to finish your answer?

THE WITNESS: I'd like to finish.

MR. LESCH: Go ahead.

THE WITNESS: That people will do things which might be considered abnormal or strange to avoid the outstretched hand of an agency that they don't want to give information to, that they feel the agency has no right to this information. It talks of individuality which I consider and I think most of us consider rather important in this country.

Q You characterize this man as dying of cancer.

A That's what I was told.

Q Would it surprise you that there was no evidence of that in the case?

MR. JAFFE: Objection.

A It doesn't really matter.

Q I think it does.

A It doesn't really matter. I think it was a dramatic example to state that he was dying of cancer. If he was a perfectly healthy human being, it would still apply.

MR. LESCH: Off the record.

(Discussion off the record.)

MR. FOGARTY: I have no further questions.

MR. LESCH: No redirect for me.

MR. JAFFE: I have none.

(Time noted: 12:00 noon.)

Subscribed and sworn to before me

this____day of_____, 1974.

C E R T I F I C A T E

STATE OF NEW YORK)
: ss
COUNTY OF NEW YORK)

I, WILLIAM BLITZ, a Certified Shorthand Reporter and Notary Public within and for the State of New York, do hereby certify:

That DR. JOSEPH MARTIN ROSENBERG, the witness whose deposition is hereinbefore set forth was duly sworn by me and that such deposition is a true record of the testimony given by such witness.

I further certify that I am not related to any of the parties to this action by blood or marriage, and that I am in no way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have here unto set my hand this 18 day of December, 1974.

WILLIAM BLITZ, CSR

I N D E X

WITNESSES

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3	Document entitled "Phase II: Practitioner Rx Nacro Flow Chart B" dated 8/7/73 (Deposition Exhibit 3),	4
3A	Same document as Exhibit 3, but dated 11/29/73 and containing additional material (Deposition Exhibit 18),	4
4	Document entitled "Schedule II Controlled Substances System, Draft 9/14/73 Phase II: System Update - Filled Prescription-Practitioners (Phase II Practitioner/Rx Work Flow Chart)" (Deposition Exhibit 3),	5

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8	Document entitled "Procedure for Daily Editing of Triplicate Prescriptions" (Deposition Exhibit 5),	6
9	Document entitled "Identification Division, Program-ID. 'H66034'" (Deposition Exhibit 6),	7
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23	Memorandum from Mr. Bellizzi to Commissioner Whalen dated June 20, 1973 (Attachment 5 with letter dated July 12, 1974 from A. Seth Greenwald, Esq. to Michael Lesch, Esq.),	13
24	Memorandum to Doctor Baker from Mr. McDermott dated October 11, 1973 (Deposition Exhibit 13),	13
25	Memorandum to Doctor Baker from Mr. McDermott dated October 23, 1973 (Deposition Exhibit 9),	13
26	Unsigned memorandum, dated June 12, 1974. Subject: Investigations going to more than one Doctor (1974) (Bellizzi 70),	14
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Deposition of Joseph Jules Wasserman.

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

- x

RICHARD ROE, an infant, by ROBERT ROE, his parent, JOHN DOE, an infant, by MARY DOE, his parent, JAMES MOE, an infant, by MICHAEL MOE, his parent, JANE POE, MATTHEW T. BRODY, ISRAEL L. SCHMIERER and EMPIRE STATE PHYSICIANS GUILD, INC.,

Plaintiffs,

-and-

GEORGE PATIENT, MARTHA PATIENT, GERALD L. LUSTIG and THE AMERICAN FEDERATION OF PHYSICIANS AND DENTISTS,

Additional Plaintiffs,

-against-

HOLLIS S. INGRAHAM as Commissioner of Health of the State of New York,

Defendant.

INDEX NO.
73 CIV 1303
(RLE-3 Judge Court)

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Deposition of JOSEPH JULES WASSERMAN, a witness, taken by plaintiffs pursuant to order, at the offices of Messrs. Shea, Gould, Climenko & Kramer, 330 Madison Avenue, New York, N. Y. 10017, on December 4, 1974, at 2:10 p.m., before William Blitz, a Certified Shorthand Reporter and Notary Public of the State of New York.

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JOSEPH BONACCI

JOSEPH L. CANNIZZARO

oOo

IT IS HEREBY STIPULATED AND AGREED, by and between the attorneys for the respective parties herein, that the sealing, filing and certification of the within deposition be waived; that such deposition may be signed and sworn to before any

officer authorized to administer an oath, with the same force and effect as if signed and sworn to before the officer before whom said deposition is taken.

oOo

J O S E P H J U L E S W A S S E R M A N, called as a witness by the plaintiffs, being first duly sworn by the Notary Public (William Blitz), testified as follows:

MR. LESCH: We have the same stipulations with respect to this deposition as we had with respect to the deposition of Mr. Rosenberg, is that correct, Mr. Fogarty?

MR. FOGARTY: That is correct, Mr. Lesch.

EXAMINATION BY MR. LESCH:

Q Mr. Wasserman, what is your profession?

A President of Computer Audit Systems, Incorporated.

Q What is Computer Audit Systems, Incorporated?

A It's a firm that specializes in auditing controls and security of computer systems.

Q How long have you been in the business of examining the auditing controls and security of computer

systems?

A The company has been in business for almost 5-1/2 years.

Q How long have you been in that business, sir?

A Prior to that, I started in computer auditing and security with the Southern New England Telephone Company in April of 1959.

Q Since April of 1959 to the present, has that been your occupation?

A Yes, it has been.

Q Are your qualifications and background set forth in this resume which I am handing to you?

A Yes, they are.

MR. LESCH: Off the record.

(Discussion off the record.)

MR. LESCH: May we have this resume of Joseph J. Wasserman consisting of four pages marked as Plaintiffs' Trial Exhibit 41 for identification.

(Resume of Joseph J. Wasserman consisting of four pages, marked Plaintiffs' Trial Exhibit 41 for identification as of this date.)

Q Mr. Wasserman, does Plaintiffs' Trial Exhibit 41 accurately set forth your qualifications in the fields of computer security, internal control

programs and the other areas of your specialization with respect to computers?

A I feel it pretty well outlines what I've done with some specific examples of experiences.

Q Is there anything that you would like to add to that resume?

A No.

Q Will you describe the type of work that you have been doing since you first entered the business of reviewing the security of various computer systems?

A Do you mean back with the Bell System? Or --

Q Back with the Bell System or at any other time where you were actually examining the adequacy of security of various computer systems.

A Well, through the last 15 years, I've been very actively involved in this particular area. Probably wrote one of the first articles on computer security which was published in the Harvard Business Review.

And in that period of time, I've not only done security work for various Bell System Companies such as the Southern New England Telephone Company, AT&T, Bell Laboratories and some of their associated companies, but I've also been actively involved for the last five

years with the General Electric Time Share Company, performing all levels of security for the time sharing network.

These activities included reviewing the physical security of their various computer centers, evaluating the procedures for security, and evaluating the security over data stored in both printed and magnetic form.

In addition to the General Electric Company, we've also done work for University Computing Company, Barnett Bank, Trans-American Corporation, United States Naval Audit Service, subcontracted work with Booz Allen where we do their security work for their clients on a subcontract basis and Babcock & Wilcox.

Some of these areas have involved looking at centers that have information that is considered top secret such as the Atomic Energy Commission.

Q In addition to the physical securities, procedural security and data security that you have described, have you been concerned with other types of protection of data from harm or unauthorized disclosure?

A Yes, we have.

In some cases, disclosure of corporate information which is considered proprietary such as

financial statements, payroll systems. Other areas, the protection of name and address lists of large companies such as AT&T, where the name and address of stockholders is considered proprietary in nature.

Access to files that are stored by various clients in the General Electric time share system. Here again to assure that either someone intentionally or unintentionally does not access somebody else's information that is stored in magnetic form in a time sharing environment.

Q What do you mean when you use the term physical security?

A Physical security is the physical sturcture of the data center, the access to the data center, fire prevention, flooding, prevention of intrusion, electrical and telephone intrusion.

Q What do you mean when you use the term procedural security?

A Procedural security is those procedures defined by a company which specifies the level of security and the methods of gaining access to a data center, getting access to information.

Q What do you mean by data security?

A Data security is the protection of data,

both in its magnetic form and printed form.

Q Did you visit the computer center of the Department of Health on January 23, 1974?

A Yes, I did.

Q What were your instructions prior to that visit?

A To observe and review the security of the facility to the best that we could under the situation, both physical, procedural and data.

Q Where was that located?

A In Albany, New York, in a building in a shopping center.

Q What parts of that building did you visit in connection with your inspection of the Department of Health's computer operation?

A We visited to start with a general office area. Then we were taken on a guided tour which included the mailroom, a coding room, the input-output area, and the computer room.

Q When you refer to the input-output area, was that the area where the key to disk and key punch operations were carried on?

A Yes.

Q Did you notice any inadequacies in the

physical security at the locations that you just described starting with the mailroom?

A Well, the mailroom which was supposed to be locked when it wasn't manned was not manned and was open.

In the coding area, the security appeared to be adequate.

The access to the input area, I would say, was inadequate because there really is no positive control over personnel entering the area. There was a man supposed to be sitting at a desk to screen people who came into this area. However, there are two entrances to the input-output area, one of which the door was left open. There was nobody by that particular door, and we were informed that the door was opened because of ventilation problems.

Q In order to maintain adequate physical security, should the door be locked?

A The door should really be locked. And there are a number of methods that can be used, either a card key system where you insert a card with a magnetic strip on it into a device which would open up the door for those people who possess the card, or a chiper lock which is a combination of keys that you would hit which if you had the right combination would allow you to gain

access.

Or the door could be electronically controlled by a guard or a receptionist when an individual walks up to the door -- obviously you would have to have a window -- would observe the individual and then release the lock.

Q Were any of those precautionary measures in effect when you saw the system?

A No, they were not.

Q Were there any other inadequacies that you observed?

A I personally feel that all employees working in an area where sensitive information is being processed should be wearing badges. My recollection is that badges were not being worn.

Also proper screening of people who are external to the State of New York such as telephone company, maintenance personnel who would work on such things as the key punch machine, the computer, maintenance people who would clean the facility should also be assigned badges.

Q Did any of the persons in the input-output area whom you observed have badges?

A Not to my recollection.

Q Did you observe whether there was any procedure pursuant to which non-employees were required to sign in and out as they entered the input-output area?

A No, I did not observe any.

Q Were there any other inadequacies that you observed in the physical security of the input-output area?

A I think those are the major ones.

Q Should there be a system whereby there are alarms on doors and the doors are crash barred for emergency exist only?

A Yes, there should be.

The ideal example is the second doorway to the input area which is supposed to be secured at all times. That particular door should be crash barred so that people can exit in case of an emergency and it should be alarmed and it should not be kept open.

Q Were any of the doors to the input-output area crash barred or alarmed in this fashion?

A No.

Q Did you also observe the computer room?

A Yes, we did.

Q Were there any inadequacies in the physical security of the computer room?

A Well, there are two entrances to the

computer room, one of which you can access from the input area, and the second is a doorway to the hall.

At the time we were there, I observed an individual come through that doorway from a common hallway. Whether he was authorized to be there, I do not know.

Again, our -- my prior remarks as far as alarming that door and it only being used for emergencies would apply to the computer room.

Q Would your prior remarks with respect to badges and the requirement that non-employees be required to sign in and out also apply to that area?

A Definitely.

If the system were implemented where only those personnel who are authorized to go into the computer room were to have a special code on their badge and wear, for example, a color badge, green or blue, whatever it is, that would be a visible as well as a positive control over those people accessing the computer room.

Q Have you finished your description of the physical description of the Department of Health's computer facility?

A Overall, it's a general office building which I believe the State of New York is the main tenant.

I didn't observe any guards or alarm systems other than the alarm system in the coding area where the prescription systems are coded, and would question maybe the overall physical security of the building. However, we did not look in that in any great detail. Though it would appear that anybody could get access to the building and once they were in the building, if they were not challenged, they could probably go to almost any area with the exception of the coding area which appeared to be adequately secured.

Q Does that complete your description of the physical security?

A Yes, it does.

Q Did you also study the procedural security of the State's system with respect to triplicate prescription data?

A To the degree which we were given information and to the degree which our questions were asked -- or answered.

Q In connection with your review of the physical security, procedural security and data security of the State system, have you examined Trial Exhibits 1 through 23 in this case?

A Yes.

Q Have you also examined Exhibits A, B and C of the State of New York which are pages 76a through 92a of the record on appeal in this case?

A Yes.

Q Did you conclude whether there are any inadequacies in the procedural security that has been established by the Department of Health in connection with the triplicate prescription program?

A Yes.

In my opinion, one area of weakness is the aspect of background checks for people working in sensitive areas.

We were informed that the check that was given was a normal civil service review of the individual; that there are really no credit checks performed, there are no drug checks performed, and there are no periodic checks performed on, say, an annual basis of people again working in sensitive areas.

This also would hold true for personnel who are non-employees of the State of New York such as Burroughs, the engineers who will work on the computer, maintenance personnel that clean, telephone company, etc.

Q Is it standard procedure to perform background checks on individuals who have access to

confidential data?

A In most businesses, it is.

Q Did you observe any other deficiencies in the procedural securities of the triplicate prescription system?

A Yes, I think there should also be a security manual designed for that particular system.

Most of the procedures alluded to various security procedures for the State of New York. It's been my experience that security manuals are very, very effective, if they are designed for that particular application and data that is going to be secured.

Q As far as you know, is there any security manual which is oriented to the particular problems of the processing of triplicate prescription data by the State?

A No. There were some general statements.

Q In Exhibits A, B and C?

A A, B and C.

And even there some of those statements are rather weak and somewhat inadequate.

For example, I believe it indicated in this particular exhibit that information should be delivered to the computer room by a clerk and returned

to that clerk. There are no sign ins for it that I have received that information or I have sent it back to an individual. So there is no positive control over the passage of information back and forth between the input area and the computer room.

Another area indicates that printouts will be delivered in a sealed envelope to the director of the Bureau of Narcotic Control. You know, here again, if this information is considered very sensitive, then there should be some more positive statement as to how the delivery should be made. In other words, is it sent through the mail? Which obviously would not be proper in this case. Or is it delivered by a guard service, which would be more proper, in that you are dealing with very sensitive information.

Q Were there any other inadequacies in the procedural security of the State's system?

A Just that I think that the manual itself is rather general and vague and does not totally apply to the given application, computer application in this case.

Q Does the manual encompass the protection of data in both written and magnetic form in the way in which you think is proper?

A Only in some cases.

I think the protection of the prescription slip itself is covered well enough in the manual in that it is locked in a vault and must be signed in for and signed out for, but when you get to the data in magnetic form or any printed report generated by the system, there is only -- it's only alluded to that it should be controlled, but nothing definitive as to how one controls it.

Q What would be a proper way of controlling the security of such data?

A No. 1 would be a positive receipt that I have a reel of magnetic tape with confidential information. It is received by somebody in the Data Processing Department.

It is then processed by him. It is then returned, and again positive receipt for its return. This at least would control the flow of information.

However, I also feel that if the information is considered sensitive in nature that when that information is processed on the computer that a management personnel who is knowledgeable in computer operations be present in the data center at that time to insure that when the information has been processed and a report has been printed that an operator doesn't substitute 4-ply

paper for it and keep two copies of the report for himself, or take that information and make a duplicate copy on a reel of magnetic tape and remove it himself.

Q Are any of those precautions present in the State system --

A No.

Q -- so far as you have observed?

A No.

Q Are there any other inadequacies in the procedural security of the State system that you observed?

A In reviewing the procedures, they indicate that information which is confidential in nature should not be divulged to any outside source. They don't say what's confidential.

In this case, they don't indicate it's the patient's name or the physician's name or the type of drug. It's not specified what is confidential.

It also -- another area is the procedures call for certain areas that are secured areas, in quotes, but they don't specify what they are. They indicate that the vault is a secured area. The vault is where they store the prescription form after it has been converted to magnetic form.

To me another secured area, for example, is

the computer room, is the input area. These are not specified, but again only alluded to in the procedures.

The last comment I have, I guess, in the area of procedural security is that when you design a system, you design a method of inputing information, the way you are going to process the information, and lastly the type of reports that you are going to get from the system. And in doing this, you evaluate at the time of system design what type of controls and security measures you must implement into the system.

In this case, if the patient's name is considered to be sensitive, then that should be encrypted or encoded so that it cannot be printed out unless somebody has basically the ability to decrypt that information.

Q To your knowledge is the patient's name that is recorded on the magnetic tape encrypted or encoded?

A No, it is not to my knowledge.

Q Mr. Wasserman, did you also examine the data security of the State's system?

A Yes, again to the degree which you can walk through and physically observe and read from the various exhibits that were made available to us.

In this area, we found a number of problems. First of all, data tapes -- data tapes representing the

information converted to magnetic form with the information about prescriptions and physicians and patient's names, if this information is considered to be very sensitive, it should be stored in a safe or a vault. We were informed that it was stored in metal file cabinets which can be broken into without too much difficulty.

The second area, Mr. Cannizzaro indicated that the hard copy, the printed output would be stored in metal cabinets in his area, and again this should be stored in some type of vault or safe.

The third, at the end of the formal working day, the data converted from a paper document -- in this case the prescription form -- is converted to magnetic form on a disk. This disk is left resident in the machine overnight, if the disk is not filled. Once the disk is filled, the information is removed and put on magnetic tape. The disk that have -- that are partially filled with information should be in a locked cabinet -- or the mini computer basically is what they use, should have the capability of having that particular disk locked.

Q Will you go on with your description of the inadequacies of the State's data security with respect to the triplicate security information?

A When a data tape, a tape with information

is to be recycled, which is basically written over, it's supposed to be degoused, degoused being the erasing of information in magnetic form.

The State of New York does have degousing equipment. However, they never test the tape to make sure that the information has been erased. And they could be putting tapes back into process that do have -- that does have information on it.

The next point as far as I can determine there are no formal procedures for shredding printouts. Security procedures indicate that when there is a large volume of confidential printouts to contact OSA, whoever that is. I'm not sure who they are.

However, when you are printing out a report in a computer room, you may print five or six pages and decide that the print ribbon has to be changed because the reports coming out are too light. Therefore, rip off the first five or six pages and just throw it in a trash can. So there is no positive procedure for destruction of hard copy here.

I already covered two other points, and that is the delivery of tapes to and from the input area to the computer room and back. That should be positive receipt.

Also the same thing would hold true for any printed report, should be signed for, as received.

I also discussed management's responsibility in being present when confidential data is being processed to be sure that it is not duplicated, to be sure that somebody is not introducing an extra copy of a hard copy.

The other area is that on every prescription form the name of the patient appears. This means that all clerical personnel who code these forms as well as all the key to disk operators who convert the data from its paper form to magnetic form will be looking at the individual names. This means that if my name appeared there as using a particular drug, why that individual would know about it, could tell my friends. You could compound that into government officials or famous athletes or movie actors or what have you, that this becomes knowledge that this particular person does take a drug.

The last area really in data security is one of going back to the design of the system. And that is when one designs a system as I indicated earlier, one also designs the output, the anticipated output of the system.

And in this case, I can only determine that a few reports have been designed. And from what I could gather discussing this with representatives of the State of New York that they really don't know in total what information they are going to really want from the system. And unless you do this at its initial stage, then I don't think you can implement the necessary security that is required in a system.

Designing security measures after the fact is costly and quite often totally overlooked.

Q Does that complete your description of the inadequacies in the data security of the system maintained by the State?

A Yes.

Q Have you at my request read Exhibit 29 in this case, which is the audit report on financial and operating practices of the New York State identification and intelligence system?

A Yes, I have.

Q Directing your attention to pages 27 through 31 of Exhibit 29, did you notice any similarities --

A Yes.

Q -- between the criticisms that were made by the State auditor of the intelligence identification

system and the deficiencies that you observed in the system of the Department of Health?

A Yes.

Q What were those, Mr. Wasserman?

A The State of New York auditors indicate a weak physical security posture. And I think basically the physical security is somewhat weak in the medical system we're talking about.

Also that there are -- is no security officer which is a point I really didn't bring up. There isn't a security officer. As far as I could determine, there is nobody trained in security for data processing which is entirely different than other aspects of security.

There is no positive screening of personnel coming in and out of the center is another point that's made here. The potential weakness because they are in a building which is not totally secured, not totally occupied by themselves. And that their employees also do not receive stringent background checks is another point that's brought out in this report.

This report also indicates a problem of controlling keys for access to the building. This is an area that we did not look into. So I could not

comment on that.

We did not visit the building after hours. We were escorted through the building. So I can't say that what we saw was the normal every day working of the center.

They also indicate a form of positive identification, a badge system be instituted as well as a card-key system be instituted.

Q You made both of those observations with respect to the Department of Health system, too, did you not?

A Yes.

Also, they indicate that there is no formal training program for all employees in the area of computer security, and this would also apply to the particular system that I looked at as far as I could determine that there isn't a formal set of procedures, a formal program which is not only given to all employees upon their arrival, but also given to them on a periodic basis.

Security in a data processing environment is not the only normal form of security that you'd find in a large warehouse where you store inventory. It's different in that a great quantity of information can be stored on a very small reel of magnetic tape which one

could put under his overcoat or just put in his briefcase and walk out of the center with. It's not like you are moving a refrigerator.

Q Did you observe whether any of the information that is kept at the Department of Health's computer center is on-line as distinguished from off-line information?

A At the center, we were informed that the Burroughs 3500 which is the type of computer that they have has various on-line applications.

Q Before we go any further, will you define on-line and off-line?

A On-line gives you the ability to acess a computer from a remote location and either update, read or create a record.

Q Would this be done, for example, by telephone?

A It is done on a terminal which is interconnected by telephone lines.

We were informed that when the prescription system is run that it is run off-line, which means that no terminal can access that particular information.

Q About how long would it take to convert the off-line system with respect to triplicate prescrip-

tion information to an on-line system?

A A week, two weeks, at the most, depending upon on how good their on-line system really is. It shouldn't be anything of any great difficulty inasmuch as they already have the capability.

Q Have you reached a conclusion as to whether the physical procedural and data security of the State's system is adequate?

A Well, in my opinion, I believe it's below average compared to other computer centers that I've been in over the last 15 years.

Q Would you say that it is adequate or inadequate?

A Inadequate.

Q In your view, is there a substantial risk of unauthorized disclosure of the triplicate prescription information that is maintained by the State at that computer center?

A Yes, from both intention and unintentional.

MR. LESCH: I have no further questions.

(Short recess.)

EXAMINATION BY MR. FOGARTY:

Q Mr. Wasserman, when you went to the facility

at Albany, were arrangements made for you to go there?

A Yes, they were.

Q By whom?

A From the State of New York?

Q Whoever made it.

A They were made by these offices, Mr. Lesch's offices. And we were taken through by Dr. Baker and some of his staff.

Q So that you just didn't walk into the building, did you?

A No, we were escorted.

Q It was actually done in accordance with either a court order or a stipulation between counsel?

A Yes.

Q So that you don't really know that the way that you went through anybody else would go through, do you?

A Well, we were escorted through.

Q But you have no reason to believe that if you had just walked up there, you could have walked through?

A Well, in my opinion, I think we probably could have.

Q But you have no reason to believe that?

A The only reason is based on my experience with locations like that in the past.

Q Have you ever inspected a data system which you found totally secure?

A No, I don't believe there is anything totally secure. I think that there are many that are quite good, though.

Q As far as printouts, you said that possibly the tape, printing tape be changed in the machine.

A I gave this as an example, that when one prints a report, occasionally the tape that is used to print, the ink in the tape becomes very light, and, therefore, the operator takes that tape off and replaces it, takes the reports that he has and just throws it in a trash can.

Q Did you observe this to happen?

A No, I did not.

Q Do you have any reason to believe that it happened at the State Health Department?

A I don't see that the State Health Department is any different than any other center. This is only one example of what may occur there. There are a number of other examples that I could give.

MR. FOGARTY: No further questions.

MR. LESCH: Off the record.

(Discussion off the record.)

(Time noted: 3:05 p.m.)

_____

Subscribed and sworn to before me

this____day of_____, 1974.

C E R T I F I C A T E

STATE OF NEW YORK)
: ss
COUNTY OF NEW YORK)

I, WILLIAM BLITZ, a Certified Shorthand Reporter and Notary Public within and for the State of New York, do hereby certify:

That JOSEPH JULES WASSERMAN, the witness whose deposition is hereinbefore set forth, was duly sworn by me and that such deposition is a true record of the testimony given by such witness.

I further certify that I am not related to any of the parties to this action by blood or marriage, and that I am in no way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 18 day of December, 1974.

William Blitz
WILLIAM BLITZ, CSR

December 4, 1974 30A

I N D E X

WITNESSES

PLAINTIFFS'	EXAMINATION BY	PAGE
Joseph Jules Wasserman	Mr. Lesch	3
	Mr. Fogarty	27

EXHIBITS

PLAINTIFFS' TRIAL		FOR IDENT.
41	Resume of Joseph J. Wasserman consisting of four pages.	

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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

- x

RICHARD ROE, an infant, by ROBERT ROE, his parent, JOHN DOE, an infant, by MARY DOE, his parent, JAMES MOE, an infant, by MICHAEL MOE, his parent, JANE POE, MATTHEW T. BRODY, ISRAEL L. SCHNIERER and EMPIRE STATE PHYSICIANS GUILD, INC.,

Plaintiffs,

-and-

GEORGE PATIENT, MARTHA PATIENT, GERALD L. LUSTIG and THE AMERICAN FEDERATION OF PHYSICIANS AND DENTISTS,

Additional Plaintiffs,

-against-

HOLLIS S. INGRAHAM as Commissioner of Health of the State of New York,

Defendant.

INDEX NO. 73 CIV 1303 (RLE-3 Judge Court)

- x

Continued deposition of JOSEPH JULES WASSERMAN, a witness, taken by plaintiffs pursuant to order, at the offices of Messrs. Shea, Gould, Climenko & Kramer, 330 Madison Avenue, New York, N. Y. 10017, on December 6, 1974, at 3:00 p.m., before William Blitz, a Certified Shorthand Reporter and Notary Public of the State of New York.

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ALSO PRESENT:

AMBROSE P. DONOVAN, JR., ESQ.

oOo

J O S E P H J U L E S W A S S E R M A N, recalled as a witness by the plaintiffs, having been previously sworn, resumed the stand and testified further as follows:

EXAMINATION BY MR. LESCH:

Q Mr. Wasserman, were you present yesterday and today during the entire testimony of Mr. Cannizzaro

and Mr. Bonacci?

A Yes.

Q Did you listen to all that testimony?

A Yes.

Q Does that testimony with respect to certain changes in the security system that has been established by the State change your conclusions as to the adequacy of the security system?

A No.

Q Will you explain why with respect to the data security, the physical security, and the procedural security in your view the State system is still inadequate?

A Well, starting from the physical security, I feel that the physical security of the building itself is quite suspect inasmuch as the computer operations is manned on a three shift, seven day basis, and apparently there are many keys to the building distributed among various employees. Plus the fact that there is no guard monitoring people coming in and out of the building.

Therefore, hard copy, tapes could possibly be removed from the building, completely unobserved by anybody.

I don't consider the procedures instituted over access to the input area-output area and the

computer room as adequate. When we assign somebody a supplementary type of function, such as sitting at a desk to insure that people sign a log to gain access to the computer room, this type of security meansure is quite suspect in my mind.

The individual obviously is working on other areas, other functions that he has, leaves his position, and anybody at that point can then walk into the center.

It's also been my experience, and one of the tests that we make in doing some of our security work, is to try to gain access to computer centers. And when you have this level of security that has been established at this location, access is generally easily gained as long as you look like you belong there.

Q Do you have any other comments with respect to the physical security that are occasioned by the testimony of Mr. Cannizzaro and Mr. Bonacci?

A Still in the area of physical security, the second door to the input-output area was described as a Dutch door where only the top is left open, at times for ventilation purposes. When we were there the entire door was left open.

Also, when we were at the facility, some-

body entered from the hallway into the computer room, thus negating the fact that that door is locked at all times.

I still feel very strongly that a formal set of controls be established over access to the area, again such as a card key system, a cipher lock system, which would require a positive act on the part of the individual to gain access to the computer room.

I also feel --

Q What do you mean by a cipher system?

A A cipher system is a small device with ten keys on them, and you punch in a code, predetermined code which allows you to gain access.

Even this is not the greatest security, but certainly better than what exists.

The most positive type of security that could be established at a center like this is referred to as a badge exchange system.

Q What is that?

A When an individual tries to gain access to the data center, a guard controls the access. Once the guard observes the individual and communicates with him -- and that's generally through some type of communication system -- it's not face to face -- he will

then allow the individual into an enclosed area.

If the person is authorized to gain access to the data center, he exchanges his ID card for a special badge, and that badge has to be worn in a visible location on the individual's person. This also provides the ability to look around a data center and see if anybody does not have a badge. If they don't, then they are challenged and removed.

Q Have you ever had experiences in connection with data centers where the management has made the statement that everyone is responsible to see to it that no unauthorized personnel are on the premises?

A Yes.

Q What is generally the result where that is the case?

A The result is twofold:

No. 1, where a company has a formal training program, has a formal set of security procedures setup in a manual, specifically designed for security, and that this manual is periodically reviewed, either on a quarterly or semi-yearly basis, and is reviewed with all new employees prior to their being allowed access, this form of control can be very effective.

In the case where companies describe their

security in written form, give it to the individual and let him sign a piece of paper, the security falls flat.

Q Would you say that the State system falls within the first category or the second category?

A The second category.

Q Have you completed your description of your comments with respect to the physical security?

A Yes.

Q Having heard the testimony of Mr. Cannizzaro and Mr. Bonacci, what are your observations with respect to the procedural security of the State's data system?

A Well, my feelings are the same as they were initially, in that again it's an area where it is inadequate.

To start with, there seems to be a great deal of confusion on the part of both of the witnesses as to what is involved in a civil service type of background check, though both are civil servants and have already been subjected to it.

Certainly there should be an awareness of what kind of information was filled out on the particular forms that they did prepare for the State. And, therefore, it's my opinion, that unless there is an on-going program of checking the background, checking credit,

drug checks, that this particular statement that the civil service checks the background of people is inadequate, and in all probability is quite ineffective.

Q Do you have any comments with respect to the use of temporary personnel in an area where the confidentiality of data is supposed to be maintained?

A That's a very dangerous situation because temporary help, especially in clerical processing type functions, are generally not of the highest caliber, or I should say maybe in many instances are not of the highest caliber, in an area that is again really suspect as being a serious deficiency in the current set of procedures or I really should say the fact that there are no procedures makes it a serious problem.

Q Have you looked at Exhibits E, H, M, I, J, K, L, N and C?

A Yes, I have.

Q Is that what you would consider to be an adequate security manual?

A Definitely not.

First of all, they are just sort of issued haphazardly. To me, a security manual has a certain continuity, defining, for example, access to the building, No. 1, who is allowed in the building, who should be in

there, what security measures they have in the building itself.

It should also outline various areas of the building.

When you get down to the data processing side, then I think it has to be established in a logical flow. First of all, what is the rationale for the handling of input media. Secondly, what level of security control should be instituted over the processing of data once it's been converted to magnetic film, and thirdly, the output of the system, again controls and security measures to be instituted there.

Not only is the document sort of haphazard, I really don't see any great continuity, and to be passing documents like this out to your people, I think it may even create somewhat of a confusion, or it could entice somebody to decide he wants to look at everything to see now what is he doing, curious seeker type.

This has to be definitive, has to tell you why, why you are establishing levels of security over processing information. And other information that you may not have security on, it should be defined as such.

Q You heard the testimony of Mr. Bonacci to the effect that there is no encrypting of patient names.

Would this be a difficult procedure to effect?

A No, there are encryption programs, computer programs that could easily do this. However, you must realize that in order for something to be encrypted, it still would pass through the clerical processing with the patient's name on it.

And it would only be encrypted when that information was put into magnetic form.

Q But this would be a safeguard of the information when it was in magnetic form, is that correct?

A Yes, that would be a safeguard.

Q By the way, where is there a greater danger of unauthorized disclosure of the information, when it is in the raw prescription form in Mr. Cannizzaro's office or when it is in the computerized form in Mr. Bonacci's office?

A As far as --

Q As far as the likelihood of obtaining information with respect to a particular individual that the curious individual was interested in.

A The easiest, of course, would be in Mr. Cannizzaro's office, the listing of patient names who had received more than a prescribed amount of drugs in a given period of time. That, of course, would be the

easiest because it would be visible to the individual.

The second, of course, is sort of a piecemeal process, and that is that all of the clerks who code or who key this information to disk would have access to names generated on a random basis. It would not be consolidated in any form. And, therefore, any public figure or friend of theirs who they saw a slip come through, they would know that they would be taking drugs.

The area of data processing is probably the most -- it is the most, I should say -- vulnerable area as far as somebody obtaining everybody in the State of New York who has had any form of drugs, because here we have stored in files a great quantity of data which is actually the history by an individual of all the drugs they have taken, and in this case I believe it will be for five years.

Now the information, of course, is on a reel of magnetic tape or would be on reels of magnetic tape, because I believe at the end of five years based on the figures testified to approximately 125,000 prescriptions per month, the final would be in the magnitude of somewhere in the neighborhood of 7-1/2 million prescriptions, which would be accumulated over a five year period.

Q Can such a reel easily be removed from the premises?

A Oh, certainly. In an attache case, under somebody's raincoat. It could be put in an envelope and mailed to somebody. There are numerous ways that a reel of magnetic tape could be actually taken from the premises.

Q Could that reel then be read by any other Burroughs 3500 computer?

A It could be read by any other Burroughs 3500 computer, or it could be read by any other computer, if there was a conversion program, a program which would convert the Burroughs 3500 tape to a tape which was compatible to that hardware.

Q Do you have any other comments on the procedural security matters that were testified to by Mr. Bonacci and Mr. Cannizzaro?

A I've already stated my feelings about a security manual. There is none.

Q Turning to data security --

A There is still a comment or two.

Q Excuse me. Going back to --

A Still on procedural security.

Q -- procedural security, what further comments do you have on that?

A An area that concerns me is the security of the data tapes with the information about all the people and doctors who have prescribed drugs. Now, these tapes are retained in a metal cabinet as I indicated before, and I feel that this really should be a secured vault, such as is used for the prescription forms.

If anything, the prescription forms might be in a metal cabinet, but certainly the tapes with all of the information, all of it, should be retained in a vault.

I also feel very strongly that the procedure should indicate that the hard copy of reports should be retained again in a vault.

I also feel that the program tape itself which has the various programs for the prescription system should also be retained in a vault when not in use.

Q Does that now complete your comments on the procedural security?

A Yes.

Q Will you tell us why the data security as testified to by Mr. Cannizzaro and Mr. Bonacci is inadequate?

MR. FOGARTY: Objection to the form of the question.

A Again in data security, we're talking about the physical storage of data in its magnetic form, the hard copy, the fact that it is not stored in a vault, that it is stored in a metal cabinet which can easily be broken into, and also another interesting observation, you can sometimes use a key to a comparable cabinet and get into it, whether it is in your office or you are in an office 3,000 miles away, as long as the cabinet has been made by the same manufacturer. We've had a number of experiences in that.

The fact that there is still in my opinion no formal procedures for shredding printouts, that I believe --

Q What do you mean by a formal procedure for shredding printouts?

A Let me look at the defendant's exhibits and I will tell you.

Exhibit K, Item 3(a) entitled "Small Volumes," this has to do with printouts. Tear off heading which identifies data and dispose of it separately. Tear and mutilate listings so it is not easily readable. Dispose of it with usual paperwaste.

To me, anything that's confidential should be shredded. That kind of procedure to me is totally

inadequate. To tear something, I can tear it in half and then just piece it back together again.

Q Would you go on with your comments with respect to the data security of the State's system?

A As far as data processing operations are concerned, inasmuch as there is so much concern over handling some of this information and keeping at least the prescription forms in a vault, to me when any report is prepared with the patient's name on it that there should be due control over the computer operations. By due control, I mean that a representative of management, and in this case probably it would have to be Mr. Cannizzaro, be present in the computer room when this listing is run, take the listing off the machine himself, so that no one else is exposed to any of the patient names in that area.

I also feel that because of the amount of sensitive data processed here that the memory of the computer should be zeroed out after the processing of the prescription system information. This would insure that none of the information that has been processed has been left in the memory unit of the computer.

Q What do you mean when you said the memory would be zeroed out?

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A It's a routine to erase everything in the memory of the computer. If you were to access the memory after a particular function, you would find what had happened with that data still stored in the memory.

This is a standard Defense Department procedure. DOD has extensive procedures on how to handle confidential or top secret data.

It also seems to me that there only seems to be procedure that really relate to the drug system, and I am somewhat amazed that there aren't procedures for other information that would be considered confidential.

MR. FOGARTY: I move to strike the last portion of his answer with regard to other information.

Q Will you continue.

A That would be the balance of data security. I do have a few other general observations.

Q Go ahead.

A One of my concerns is the fact that there is not an on-going program for computer security at this location. And by instituting an on-going program, this will assist people in not forgetting that they are working with confidential data.

An on-going program in security also would affect those new hires or temporaries or non-New York State employees who have access to the various secured areas of the building.

It's been my experience that if you don't have an on-going security program which would be conducted by people who have been formally trained in this field, that security will be forgotten by the individuals at the location.

Q What do you mean when you say formally trained?

A By formally trained, there are a number of seminars that are conducted, in some cases by the computer vendor that can be available in the commercial market that instruct the person for a three to five day period on the problems of computer security, and the problems of computer security are generally broken down into three classifications: The physical aspect, the procedural aspect and the data security.

They've also recently included another aspect and those are threats, what type of threats can you expect.

Q Do you have any further observations with respect to the three types of security of the State system?

A I guess the other comments I have is to the effect that I guess the prior two witnesses seem to be somewhat confused as to really what level of security did exist at the center.

Q Why do you say that?

A For example, I believe a question asked of Mr. Cannizzaro yesterday was a question to the effect are there any signatures for receipt of the prescription reports, and his answer was no, and yet one of the exhibits that we saw did refer to a signing off on the receipt of the prescription reports.

Q Mr. Wasserman, do you consider the computerization of large amounts of information as a threat to the privacy of the individual?

MR. FOGARTY: Objected to.

A I certainly do.

Q Will you tell us why the computerization of information in your opinion constitutes a threat to privacy?

MR. FOGARTY: Objection.

A The computerization of information in this particular case means that large quantities of data will be stored on a few reels of magnetic tape which would give you the entire history of the pattern

of, in this case, taking drugs of the people in the State of New York. And again on several reels of tape, we could have any person who has taken drugs over a five year period. And this information obviously can easily be taken out. In its paper form it becomes more difficult because one would then have to go through 7-1/2 million forms and collate this information in order to get a pattern, for example, on an individual.

Q Mr. Wasserman, did you hear Mr. Bonacci testify that he did not consider the computerization of information such as the triplicate prescription information to constitute a danger to the privacy of the individual?

A Yes, I did.

Q In your view, if an individual who does not recognize this danger is in charge of computerized information, does that in itself have an affect on the ability to maintain the confidentiality of the information?

A It certainly does.

Q Will you explain why?

A Because that person, whoever he may be, or she may be, is not going to be thinking about securing information. He is going to be concerned about productions and budgets and personnel reviews, and not concerned

about the problem of privacy or security or controlling that particular data, unless it's being emphasized by their management.

MR. LESCH: That is all.

EXAMINATION BY MR. FOGARTY:

Q Mr. Wasserman, with regard to your concern for privacy and the invasion of it, I think you said that there were massive amounts of information and that the concern should be rather with the tapes than with the prescriptions themselves.

Is that a fair statement of what you said?

A No. I'm saying that one can obtain massive amounts of information from the tapes versus only information on a piecemeal basis with the prescriptions. Certainly there should be security over the prescriptions.

Q Do you know whether the same information is contained on the tape that is on the prescription?

A According to the Exhibit F which lists the patient's name, doctor's identification, drug code, pharmacy code, date the form was filled out, date the prescription was filled, batch number and serial number, I think that's quite a bit of information, unless the report is fictitious.

Q Would you take the first name on there,

please, Mr. Wasserman.

A The name is Aaron.

Q What else?

A Initial Z. His age is 47. His zip code --

Q Where does he live?

A He lives in a zip code area.

Q Which one?

A Zip code 10970.

Q Where is that?

A Beats me.

Q What is the name of his doctor?

A Doctor has code D with a number on this report. However, there are other reports with the doctor's name on it.

Q What is his doctor's name?

A It doesn't say on this report.

Q Where is his doctor?

A Also does not say.

Q What pharmacy did he fill the prescription at?

A It doesn't give the pharmacy's name either.

Q Do you know the location of the pharmacy?

A Not on this report.

Q When was the prescription filled?

A When was the prescription filled?

There is no date for Mr. Aaron. That would mean that it was filled by the physician.

Q It would?

A Well, then the form was not filled out properly. Because on all others it indicates the date filled out.

Q Let us take one with a pharmacy.

Mr. Abbey or Abbey R. Abbey is the name, R is the initial. It was filled out on April 24, 1974 and again on May 21, 1974.

Q Where?

A It doesn't indicate the name of the pharmacy on this report.

MR. JAFFE: I would like to ask that the reference to the names be struck from the record.

MR. FOGARTY: Fine.

MR. JAFFE: They can be referred to by initial or by the number on the page.

And I think that should be done by agreement to strike it clean from the record.

MR. FOGARTY: All right.

THE WITNESS: I will refer to

this one as No. 3. The first one would be No. 1 that I referred to.

Q Mr. Wasserman, from what you have just told us, what do you know as a result of this computer information?

A I know a person working -- living -- sorry -- living within a certain zip code has taken a drug.

Q What drug?

A I can't tell you because I don't have the code identification which is on another report.

Q It is on another report?

A I believe or it would be in your procedures as to what the codes are. In order for this particular form to be prepared, the original prescription must be coded with that code for that particular drug.

Q So with this report, in order to make it meaningful, you are going to have to burglarize more than one part of this operation, aren't you?

A Not necessarily.

Q You just burglarized hypothetically the computer information. What are you going to do with it?

A In its printed form. If I happen to live in a given zip code and I know that No. 3 and it's --

Q I am not asking you --

MR. LESCH: I ask that you permit the witness to finish his answer.

THE WITNESS: If I know No. 3 lives in my zip code, I would know that No. 3, whoever he or she may be, is taking a drug.

Q What drug?

A Again, if I have access to the center and get access to the information, or if I worked in that center, the code for the drug would probably be known to me.

Q It would be known to you?

A Certainly.

Q Was there any evidence either from Mr. Cannizzaro or Mr. Bonacci that the clerks who put this information into the computer knew anything about the drugs?

A They certainly would have to know that if a drug was morphine and was coded 01 that a person who had an 01 is getting morphine. They'd have to know both sides. They must know both sides.

Q Would the computer people have to know that?

A Anybody who programmed this, yes.

Q They would have to know that?

A They certainly would in order to write the

program. They would have to know what his 01 is equal to and it would have to be part of programming documentation which is normal standards for any program.

Q The person programming the machine couldn't program it without knowledge of what the numbers specifically meant?

A It could be programmed without specific knowledge of what the code was. However, in order to have proper program documentation which substantiates what the program is doing or is supposed to do, the list of drugs and the related code must be in the documentation. This is a standard, it is an accepted standard in the data processing field.

Q You are saying, Mr. Wasserman, that a machine cannot be told to bring out all information with regard to No. 1, with regard to, say, drug No. 5 or his use of No. 5 without that machine knowing what No. 5 is?

A The machine does not know what No. 5 is. The programmer who programs the machine must know what No. 5 is.

Q Why must he?

A In order to write a program, and in order to document it so that if anything were to happen. For example, if a set of conditions occurred in the computer

at a given time, and the program ceased to run, somebody would have to come in and fix the program. Without the documentation, this would be totally impossible.

Q You are sure of that?

A I'm positive of that.

Q The programmer then must know what every digit on this sheet means, is that correct?

A Yes, in order to write a program to come out with this report obviously he'd have to know.

Q Would anybody other than the programmer have to know?

A The people who encode the prescription with a code number for the drug would have to know.

Q They would have to know every code number on the sheet?

A No.

Q They simply would have to know the code number for the drug being prescribed?

A In order to code the document so that it can then be key punched.

Q So that's two places where part of the information would be, correct?

A That is correct.

It would also be known in Mr. Cannizzaro's

group. In order for them to interpret the report, they would have to be aware of what the codes represented as far as the drugs are concerned.

Q As Mr. Cannizzaro testified he is the one who interprets those reports, did he not?

A He did not.

Q He didn't?

A He also said his clerk interprets the reports.

Q You have a different understanding of his testimony than I do, but be that as it may --

A I may be wrong, but I was under that impression.

There would also be various management people throughout this department who would know what the codes are, such as Mr. Bonacci.

Q Mr. Bonacci knows what these codes are?

A I'm sure he must know what they are.

Q Did he say that?

A He did not say it, but I would assume that he --

Q But you are jumping to the conclusion that he does?

A Well, if I were managing that particular

department, I certainly would know what they are.

Q You would?

A That's correct.

Q Let us suppose that they wouldn't tell you what they meant.

MR. LESCH: Mr. Fogarty, national drug code numbers are published publicly available information as you know and I know.

MR. FOGARTY: There is more than national drug codes on here.

MR. JAFFE: Yes, but you are referring to the knowledge of what the drug is and if it is public knowledge because it is a national drug code, then you would not have to rob anything. You could go to the national drug code and look it up. It's public information. And zip codes are similarly public information.

Q Could you run the computers without the information?

A You can't run a computer without information.

Q I am talking about your personal knowledge of what this printout says. Can the computer be run with-

out your personal knowledge of it?

A Well, the question is one that --

Q No, the question is the one I asked you.

MR. LESCH: I object to the form of the question.

MR. JAFFE: I object to the form.

MR. LESCH: By run the computer, do you mean obtain information from the computer or do you mean put information into the computer or do you mean something else?

MR. JAFFE: In addition to that --

MR. FOGARTY: I would like the witness to answer my question first.

MR. LESCH: I object to the form of your question, but if the witness understands it, he may answer it.

A Assuming that I was in the computer room at the State of New York, I would take the run book which tells you where to mount tapes, how to activate this particular system, and yes, I could run it. Because there should be instructions for an operator and they would be in the computer room for running the prescription system.

Q Would that operator know what was coming out of that machine on a printout?

MR. LESCH: I object to the form of the question.

A He would know the particular application. It would depend on the level of documentation left in the computer room. If there was adequate documentation there, he might know everything. If the documentation was not proper, then he might not know everything.

Q In fact, Mr. Wasserman, as far as the operator of the machine is concerned, this printout can come out and he may not know anything on it, right?

A Well, the recognizable fields on this particular document that we're discussing, Exhibit F, happens to be the patient's name. If the patient were known to him, then obviously he would know that they take a particular type of drug. The type of drug he may not know. The particular document is entitled "Patients With Rx Total Dose In Excess Of 30 Day Supply Processed In The Month Of" blank.

So that he would know that this is an exception report, and that an individual, whether he personally knew them or they were a famous person for one reason or another, political, sports, he would be aware of their name and the fact that they are taking a drug, and they have greater than a 30 day supply of that

particular drug.

Q Would it be accurate to say that he knows that a person with the same or similar name to someone he might know or know of took a drug?

A On this particular report, only if it exceeded a 30 day supply.

Q Fine. And that they had in their possession or were prescribed in excess of a 30 day supply.

A On this particular report that we are discussing, yes.

Q When you were talking about physical securities, you said there were a number of cases of break-ins into areas controlled by keys by people having keys to similar locks thousands of miles away. Would you tell us of some of those, please?

A The reference was being made to standard type file cabinets. We have personally had several experiences, one with a bank in Southern California, where I keep the key to a cabinet from our office, and in jest just tried a cabinet of the same make and it opened. This is a very common type of a problem that is always looked into by people in the security field, when it comes to the protection of vital information, stored in standard file cabinets or supply cabinets.

I think if you checked a lot of your security magazines, you will find that this particular item is generally discussed in writing.

Q What specific cases have you handled involving that?

A We have one with a bank in California.

Q You just mentioned that.

A The second one is with a time sharing company in the Midwest.

And the third with U. S. Naval Audit Service in a job that we did for them at one of their locations.

These are three experiences that I've personally had.

Q Where do the keys come from that open these cabinets?

A In the second two cases, the time sharing company and the governmental agency, they were keys that were at that location that were not supposed to open up these particular file cabinets.

Q They were there?

A They were at the location.

Q They were not 3,000 miles away?

A No.

Q When you referred to zeroing out the memory of the computer, exactly how is that done?

A That is done by introducing into the system a small program which will zero the memory, basically erase the memory. The reason why they call it zero is that's the way the memory takes shape.

Q In other words, you run this program through until you come on the printout with a line of zeros?

A If you went into the memory of the computer and said "Printout everything in memory," you would then come out with all zeros, meaning there was nothing there.

This is a very common security measure, especially in time sharing.

Q What would precede the zeros?

A What would precede them?

The information that was there.

Q How much information?

A Well, it could be, depending on the size of the memory, it could be anything from 4,000 characters of information to as large as the memory is, 248,000, 526,000, depending --

Q How large a memory does the computer of the Department of Health has?

A I'm not sure what the core size is.

Certainly the machine at the Department of Health would have to have at least 64,000 characters or 64K machine, minimum.

Q But that's an assumption on your part.

A It's not an assumption. In order for it to run in an on-line mode, it would have to have to have 64K and in all probability 128K.

Q If it isn't running on an on-line mode --

A It still would have the same thing. You wouldn't cut it off.

Q Does one have to prepare a program in order to get this so-called retained memory out?

A Possibly. It would either be written by yourself, it may be a program that the vendor would supply you as part of his standard programs that he supplies any user, or it could be purchased commercially.

Q But there must be a program?

A That's correct.

Q In other words?

A That's correct.

Q It just does not come out?

A No, sir.

MR. FOGARTY: No further questions.

MR. LESCH: That is all.

(Time noted: 4:10 p.m.)

_____

Subscribed and sworn to before me

this____day of_____, 1974.

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C E R T I F I C A T E

STATE OF NEW YORK)
: ss
COUNTY OF NEW YORK)

I, WILLIAM BLITZ, a Certified Shorthand Reporter and Notary Public within and for the State of New York, do hereby certify:

That JOSEPH JULES WASSERMAN, the witness whose deposition is hereinbefore set forth (pages 31 to 64A), was duly sworn by me and that such deposition is a true record of the testimony given by such witness.

I further certify that I am not related to any of the parties to this action by blood or marriage, and that I am in no way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 18 day of DECEMBER, 1974.

WILLIAM BLITZ, CSR

BEST COPY AVAILABLE

363a

Deposition of Defendant, State of New York.

SOUTHERN DISTRICT OF NEW YORK

- x

RICHARD ROE, an infant, by ROBERT ROE, his parent, JOHN DOE, an infant, by MARY DOE, his parent, JAMES MOE, an infant, by MICHAEL MOE, his parent, JANE POE, MATTHEW T. BRODY, ISRAEL L. SCHNEIDER and EMPIRE STATE PHYSICIANS GUILD, INC.,

Plaintiffs,

-and-

GEORGE PATIENT, MARTHA PATIENT, GERALD L. LUSTIG and THE AMERICAN FEDERATION OF PHYSICIANS AND DENTISTS,

Additional Plaintiffs,

-against-

HOLLIS S. INGRAHAM as Commissioner of Health of the State of New York,

Defendant.

INDEX NO. 73 CIV 1303 (RLE-3 Judge Court)

- x

Deposition of defendant, STATE OF NEW YORK, by JOSEPH L. CANNIZZARO, taken by defendant pursuant to order, at the offices of Messrs. Shea, Gould, Climenko & Kramer, 330 Madison Avenue, New York, N. Y. 10017, on December 5, 1974, at 9:45 a.m., before William Blitz, a Certified Shorthand Reporter and Notary Public of the State of New York.

List of Changes
Joseph L. Cannizzaro - Transcript
12/5/74

	Location	Change	Reason
1.	Page 19 Line 18	Item 33 to 83	Correction
2.	Page 26 Line 26	Section 33.71 to 3371	Correction
3.	Page 90 Line 18	Section 33.71 to 3371	Correction
4.	Page 90 Line 25	Section 33.71 to 3371	Correction
5.	Page 91 Line 1	Section 33.71 to 3371	Correction
6.	Page 92 Line 10	Section 33.71 to 3371	Correction
7.	Page 114 Line 24	Section 33.71 to 3371	Correction

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AMBROSE P. DONOVAN, JR., ESQ.

JOSEPH BONACCI

JOSEPH JULES WASSERMAN

oOo

IT IS HEREBY STIPULATED AND AGREED, by and between the attorneys for the respective parties herein, that the sealing, filing and certification of the within deposition be waived; that such deposition may be signed and sworn to before any

officer authorized to administer an oath, with the same force and effect as if signed and sworn to before the officer before whom said deposition is taken.

oOo

J O S E P H L. C A N N I Z Z A R O, called as a witness by the defendant, being first duly sworn by the Notary Public (William Blitz), testified as follows:

EXAMINATION BY MR. FOGARTY:

Q Would you state your name, please?

A Joseph L. Cannizzaro.

Q By whom are you employed?

A New York State Health Department.

Q In what capacity?

A Currently the director of the Bureau of Controlled Substances Licensing.

Q What is your background, educational and work background?

A I graduated from the University of Buffalo, College of Pharmacy in 1942, and was licensed as a pharmacist by the State of New York in 1942, September thereof.

I entered military service at that time

and was discharged honorably in February of 1946.

I went into the private practice of pharmacy and remained there until May of 1947 when I began my employment with the State of New York, Bureau of Narcotic Control, as a narcotic investigator.

Q How long were you a narcotic investigator?

A Until 1959, at which time I was promoted to the position of senior narcotic investigator.

Q What exactly does a narcotic investigator do, Mr. Cannizzaro?

A Basically, he conducts investigations and inspections with regard to the implimentation of the provisions of Article 33 of the Public Health Law of the State of New York, which is commonly known as the New York State Controlled Substances Act.

Q You mentioned Article 33. You are talking about the current law?

A That's correct, sir.

And prior to that, of course, it was two separate laws, Article 33 and Article 33(a).

Q What sort of investigations did you handle?

A The investigations would primarily relate to inspections with regard to applications that were submitted for license, and then any violations or

suspected violations with regard to narcotics and depressant stimulant drugs which are now commonly referred to as controlled substances.

Q During your investigative days, how did the Department become aware of violations or prospective violations, possible violations of the law?

A Primarily through the inspection of pharmacy prescription files, supplemented by information that might be received from various sources, pharmacies, physicians, hospitals, and citizens, husbands, wives.

Q How many narcotic investigators are there in the State of New York?

A At the current time, I believe that there are about 24.

Q They cover the entire State?

A Yes, sir.

Q Are most of them in the City of New York?

A Yes, sir.

Q What was your next position with the Department of Health?

A In 1959, I became a senior narocitc investigator assigned to the New York City office. I think that was in June.

And in November, I was transferred to the

central office in Albany as the senior narcotic investigator. In fact, that was the only senior narcotic investigator position at that time. So that I functioned primarily in a supervisory and administrative capacity in the central office.

Q How long did you hold that position?

A In 1969, I was transferred to the Albany regional office of the New York State Health Department.

Q What position did you take there?

A As a senior narcotic investigator.

Q How long were you there?

A I was there until January of 1974, when I became the acting director of the Bureau of Controlled Substances Licensing.

Q What are your functions in that position?

A As director of the Bureau, I'm responsible for four major programs, the triplicate prescription program, general licensing, methadone maintenance and reports and NC-9 reports or physician-patient reports.

Q You said that you had jurisdiction over the triplicate prescription law.

A I'm responsible for the sales or distribution of the triplicate prescriptions to the various authorized practitioners and institutions, and then for

the receipt and processing of the filled triplicate prescription copies that are submitted by pharmacies and dispensing practitioners.

Q How do pharmacies and dispensing practitioners obtain the forms?

A They submit an application together with the appropriate fee to our unit, and we then distribute the forms to them.

Q Do you keep records as to what forms are dispensed to whom?

A Yes, sir, we do.

Q In other words, you know which doctors have his forms?

A Yes, sir.

Q What is the purpose of keeping that record?

A To keep a very firm control over the distribution of the triplicate prescription forms, to know exactly to whom a given set of forms have been sold or distributed.

Q Of what value is that information?

A Other than the record keeping aspect of it, it enables us to follow-up in situations where forged prescriptions are involved or any deviation from the statutory requirement is involved.

We will always know to whom that particular prescription document was furnished.

Q When the doctor writes or prescribes a Schedule II drug and uses a triplicate prescription, what exactly happens from the moment he writes the prescription?

A When he executes the prescription, it's executed in triplicate. If the prescription is to be filled by a pharmacy, he snaps out the form which releases the original and third copy and he gives that to the patient.

The patient takes those two copies to the pharmacy where the pharmacy fills the prescription, keeps the original copy, after he has made the required notations thereon, and submits the third copy to the State Health Department -- that would be to our particular bureau -- by the 15th of the month following the month in which the prescription was filled.

If it is a dispensing practitioner, that is, where the practitioner dispenses the medication to the patient, he snaps out the form and submits the original and third copy to our Department as the pharmacies have by the 15th of the month following the month in which he dispensed the medication to the patient.

Q You said as the pharmacies had. The pharmacy does not send you the original prescription, do they?

A No, sir, they keep the original on their file.

Q In other words, your reference was to the third copy?

A In the case of the pharmacies, yes, sir.

Q What happens to the third copy of the prescription when you get it?

A In those instances where it is submitted by pharmacies, they enter -- when they are received, they enter our regular processing procedure, which means that they are taken out of the envelopes by the processing clerks, setup in a file, face up and in order as received, and are then coded and edited and batched and ultimately sent to the Data Processing Unit.

In the instance where it is dispensing practitioner, the first thing that is done is the removal of the third copy of the prescription, because he submits the first and third copy, and that third copy is shredded and then the original prescription is processed along the same manner as the prescription copy submitted by pharmacies.

Q Who does the sorting of the prescriptions?

A The supervising prescription clerk has the overall responsibility for overseeing that operation.

The prescription batch and edit clerk will open the envelopes and arrange them in trays as received, first in-first out.

And then they are turned over to the coding and editing clerks for their routine processing.

They are then thereafter placed into batch and entered into a batch log logbook by the supervising prescription clerk, after which they are logged out to Data Processing Unit and logged back in from Data Processing Unit and placed in our security vault.

Q When you send the prescription forms to the doctors, is there any type of return envelope sent with them?

A No, sir.

Q In other words, they submit them in their own envelopes?

A That's correct, sir.

Q And they are told what address to send them to?

A Yes, sir.

Q Directing our attention to the building

in which you are located for the moment, where is the building?

A The address is 845 Central Avenue, Albany, New York.

Q Where physically is it?

A It's located to the rear of 855 Central Avenue, which is an office building and adjacent to 875 Central Avenue which is an office building, I believe primarily occupied by the -- a unit of the State Motor Vehicle Department.

Q The building in which you are located, are there any occupants of that building who are not employed by the State of New York?

A No, sir, I don't believe that there are any other occupants. I think the building is occupied solely by the State Health Department and the State Department of Commerce.

Q After the prescriptions are sorted, what happens to them? These are original prescriptions we're talking about, correct?

A They will be the original copy in the instance of the dispensing practitioner. They will be the third copy in the instance of those prescriptions that have been filled by pharmacies, the pharmacies

retaining the original prescription.

Q They are both treated the same?

A That is correct, sir.

Q What happens to them?

A In the processing by the processing clerks, they scan the prescription to make certain that the practitioner's BNDD number is located.

Q What is the BNDD number?

A That is a number that is assigned to a practitioner upon application by the drug -- Federal Drug Enforcement Administration, which authorizes the prescribing of controlled substances by that particular practitioner.

Q What does BNDD mean?

A That is an acronym for Bureau of Narcotics & Dangerous Drugs, which is now identified as the Drug Enforcement Administration.

The next thing that is done in the coding and editing process is to sort of clarify if it is necessary the total quantity that is prescribed on the prescription and edit that in a special manner, if it needs editing, and the same thing with the maximum daily dosage. They also check and will clarify the pharmacy, the pharmacy BNDD number, as well as the NDC number of

the controlled substance that has been prescribed, if it is on our special list of controlled substances. Otherwise, the NDC number remains untouched.

That is the essence of the --

Q That finishes the sorting clerks --

A Operation.

Q Where are these clerks located?

A They are located in our security area which is separated from our administrative area, and within this area they operate behind a security fence.

Q What kind of a fence?

A It is a chain link fence that runs from floor to ceiling.

MR. LESCH: May I have the last two questions and answers read back, please?

MR. FOGARTY: Surely.

(Read record.)

MR. LESCH: Off the record.

(Discussion off the record.)

BY MR. FOGARTY:

Q How many clerks are in there?

A Nine.

Q Are they civil service employees?

A They are all civil service employees with

the exception of two temporary service clerks that are hired through our personnel office.

Q As to the civil service employees, what type of investigation is made before they are hired?

A I believe it's the usual type of investigation that's conducted with respect to all State employees. I do not know the complete nature of that.

Q Do you know anything about it?

A I believe there is an investigations unit within the Civil Service Department itself. I know I was subjected to it myself.

In other words, anything that you state on your application is subject to being verified and checked upon, your application for State employment.

Q Is there any investigation made outside the department?

A I do not know that, sir.

Q You get the prescription coded, edited. What happens to it then?

A They are placed in batches by the supervising prescription clerk, and they are given a sequential number, and then placed in cabinets that are identified as to be key punched.

When the Key Punch Unit notifies our

department -- our bureau that they are ready for an additional supply of batch prescriptions for key punching, the supervising clerk extracts the batches, which average approximately 50 a day and logs them out to the Key Punch Unit.

When they are through with the processing, they notify her and she picks them up and logs them back into our batch record book and places them in cabinets within our security vault in batch number sequence.

Q They are not sent to the key punch operators until you receive notification that they are ready to receive them, is that correct?

A That's correct, sir.

Q Then they are kept locked when they are in your possession?

A Yes, sir, they are kept prior to going to key punch in our security area. After they come back from key punch in our security vault.

Q The security area to which you refer is the area where the coding clerks are behind this wire fence?

A That's correct, sir.

Q Is there any additional security involved with that wire fence?

A There is a central station alarm system that applies to both the security area, the entire room in which the security area is located, and the security vault.

Q Where is the security vault?

A The security vault is approximately about 20 yards from the security area down the corridor.

Q What type of a place is it?

A It's a concrete block wall room with a steel door and lock.

Q The door to this vault area, is it opened or locked?

A It's locked at all times when not in use.

Q Who has keys to it?

A The key is in the direct -- under the direct personal control of the supervising prescription clerk.

Q Is she the only one who has access to it?

A Outside of myself, she is the only one who has access to the key. And if I want it, I have to go to her.

Q Where is that key kept when she is not available?

A It's kept in the security room in a book

attached to the key ring. That's the vault logbook.

Q What kind of access is there to the security room where the prescriptions are coded?

A All of our bureau employees have access to that area in the course of their official duties.

Q How is entrance obtained?

A They may walk in and out of that area through a latch locked gate.

Q Is there anybody supervising their coming and going?

A The supervising prescription clerk.

Q And in her absence?

A The batch and edit clerk, or any other person that I may specifically designate.

Q Do their positions in the room give them full view of the entryway?

A Yes, sir.

Q Is that the only entryway to that room?

A Yes, sir.

May I supplement that?

There is another entry door, but it's never used. It's always kept locked. So it's the only entry-way that is used.

Q Where does the other door go?

A It goes into a supply room to the right of the main entrance of our security area in which we keep, oh, our backup quantities of envelopes and forms, and other supplies.

Q When the triplicate prescription law became effective, did you cause any instructions to be issued with regard to the handling of them?

A I did not, sir, because I was not in that capacity at that time. That became effective April 1, 1973.

Q Were there instructions in effect at that time?

A I believe there may have been, but I'm not aware of them.

Q Is there a manual?

A Yes, sir, we do have a manual that relates to the security of information from unauthorized disclosure.

Q I show you a document entitled "Administrative Policies, Procedures and Forms, Office Practice" dated March 22, 1973, and I ask you if you are familiar with that.

A I've seen this, but I'm not familiar with it.

Q You have seen it, though?

A Yes, sir.

Q I show you a memorandum dated March 8, 1974, and ask if you are familiar with that.

A Yes, sir, I am.

Q What does that relate to?

A The memorandum is entitled "Confidentiality of Records" and it's a memo from me directed to all non-bureau employees.

Q I show you a memorandum of March 11, 1974. Are you familiar with that?

A Yes, sir, I am. That is a memo entitled "Confidentiality of Records" from me addressed to all employees in the Bureau of Controlled Substances Licensing.

Q What does that have reference to?

A I advised them of their responsibilities with regard to confidentiality and relate specifically to GA Manual, Item 33.

Q Is this the item to which you refer?

A Yes, sir.

Q That is dated --

A February 27, 1974.

And in it they are requested to read it and then acknowledge the fact that they've read it by signing the attached sheet. And that they understand it

and will comply with the requirements as set forth in the GA Manual item.

MR. FOGARTY: I would like the three documents marked Defendant's Exhibit 1.

MR. LESCH: Why don't you call them Defendant's A, B and C.

MR. FOGARTY: Fine. You designate the order.

MR. LESCH: It does not matter to me.

MR. FOGARTY: All right, mark them 1, 2 and 3 in the order I gave them to you.

MR. LESCH: Since ours are marked 1, 2 and 3 --

MR. FOGARTY: A, B and C.

MR. LESCH: Yes.

(Memorandum dated March 8, 1974 entitled "Confidentiality of Records" from Joseph L. Cannizzaro to all non-bureau employees, marked Defendant's Trial Exhibit A for identification as of this date.)

(Memorandum dated March 11, 1974 entitled "Confidentiality of Records" from Joseph L. Cannizzaro to all employees in the Bureau of Controlled Substances Licensing, marked Defendant's Trial Exhibit B for identification as of this date.)

(Document headed "General Administration Manual" dated 2/27/74, Item 83, marked Defendant's Trial Exhibit C for identification as of this date.)

MR. LESCH: Off the record.

(Discussion off the record.)

MR. LESCH: If we were before the court at this time, I would object to the admissibility of any of these documents in evidence. They are not on the schedule of defendant's exhibits.

Moreover, Exhibit C which is the general administrative manual and which was referred to in the schedule of defendant's exhibits that I obtained from Mr. Greenwald, which was inserted into the pretrial order, and which was signed by the Attorney General's Office, referred to specific pages of the record on appeal, the general administrative order that was dated October 16, 1972.

Now for the first time at the trial of this action, I am handed a document that I have never even seen before dated February 27, 1974 and we have received no advanced notice of this document and it is

not even referred to in the stipulation pursuant to which this case is being tried.

I might say that the first time I saw Exhibit C was just a few moments ago when a copy of it was given to me by Mr. Fogarty.

MR. FOGARTY: I would suggest, Mr. Lesch, that you check your records and find out if you didn't get a copy of it about two weeks ago. I think you got copies of all of these documents that I have in front of me two weeks ago.

MR. LESCH: Sir, I got copies of Exhibits A and B.

MR. FOGARTY: If you got A and B, you also got C, because they all came to me together.

MR.LESCH: With a letter from Mr. Greenwald dated June 25, 1974.

I did not get a copy of Exhibit C until this morning.

MR. FOGARTY: I have a different understanding.

MR. LESCH: You may be interested

to see the list that I obtained from Mr. Greenwald which contains what are now Exhibits A and B, but which has no reference to what is now Exhibit C. And I can tell you that I received this list together with his letter dated June 25, 1974.

MR. FOGARTY: What does the first sentence of Paragraph 2 of the memorandum of March 8, 1974 say?

MR. LESCH: I have read it.

MR. FOGARTY: What does it say? What does it refer to?

MR. LESCH: It was never provided to me.

MR. FOGARTY: You said you never saw a reference to it. There is a reference to it right there so I am inclined to think that you had a copy of it.

MR. LESCH: I said that this Exhibit C was never provided to me before, and it hasn't been until this morning.

MR. JAFFE: Furthermore, may I point out that the objection is based on the fact that there is a list of defendant's

exhibits which were submitted in the pretrial order which does not include any of these as I understand it.

MR. LESCH: That is correct. There is no basis for offering these documents in evidence now when the Attorney General's Office signed a pretrial order in which there was no reference made to any of them. The court directed us to submit a list of all our exhibits.

MR. FOGARTY: And our witnesses, I might point out, Mr. Lesch.

MR. LESCH: Yes, that is correct, and our witnesses.

MR. FOGARTY: Right.

MR. JAFFE: I would like to set the record straight on the witnesses. We informed the Attorney General that there was a change in one or two witnesses and no objection whatever was made.

MR. LESCH: Moreover, we explained the only additional witness that was offered by the plaintiffs that I represent was Dr. Fishman, and I explained to the court and the Attorney

General that Dr. Fishman had been away for a number of weeks prior to the Thanksgiving Day holiday and that the first time I heard from him was during that holiday and as soon as I heard from him I advised the court and the defendant that we intended to offer Dr. Fishman's testimony and no objection was made thereto.

MR. FOGARTY: That advice was given on the morning of the trial.

MR. JAFFE: As for the co-plaintiffs, the only witness who was additional was a cancer patient who was initially said to be too sick to testify, but subsequently -- and at that time we notified the Attorney General we might have to take a deposition of that plaintiff, but subsequently his doctor permitted him to come and testify and we so informed the Attorney General.

MR. FOGARTY: Did anybody say anything about your witness?

MR. JAFFE: No. I want to make that clear. There was no objection whatsoever to that change.

MR. FOGARTY: Shall we now proceed?

MR. LESCH: Are you waiting for an answer from me?

MR. FOGARTY: Yes.

MR. LESCH: Sure.

MR. FOGARTY: You are finished?

Okay.

BY MR. FOGARTY:

Q Mr. Cannizzaro, in both of your memos you are talking about confidentiality, is that correct?

A That's correct.

Q Why?

A Because of the confidentiality requirement of the statute, Section 33.71 of the Public Health Law, the GA Manual item that relates to confidential documents and to make all of our employees aware of the fact that these are sensitive documents and that the information contained therein should not be communicated to anyone during the course of their employment with our bureau.

Q In the operation of your office, do you do anything to enforce or to impress this on the employees?

A Yes, sir. Our processing manual contains continual reference to the fact that the documents contain confidential data and should not be discussed with anyone, even among themselves.

MR. LESCH: I move to strike any reference to a processing manual, since there is no such document in evidence. If there is such a document to be offered in evidence, it will speak for itself.

MR. FOGARTY: Would you read back the last answer, please.

(Read answer.)

Q Do you have each employee do anything with relation to this matter?

A Yes, sir.

After reading the GA Manual, Item 83, I believe is the number, they sign a statement to the effect that they are aware of the contents of that GA Manual item which relates to confidentiality of data, and that they will agree to abide thereby.

Q Is this information transmitted to all employees as they are employed?

A Yes, sir.

Q Are they asked to sign the statement?

A Yes, sir.

Q Where are those signatures kept?

A They are kept as an attachment to that particular memorandum that has been previously referred

to here, the confidentiality memos.

Q Have you had any occasion to date where you have become aware of anyone violating this confidentiality?

A No, sir, I have not.

Q With regard to the vault area and the security area, have you got any standing instructions?

A We have a visitor's log to the security area wherein the supervising clerk enters any -- the entry of any person into that area that has authorization to come into the security area.

He also maintains a vault entry log to indicate entry into the vault.

Q What by definition would be a visitor to that area?

A No visitor -- let me put it this way.

Our regular bureau employees have access, may enter into the vault area -- into the security area in the course of there official duties. Also non-bureau employees that have been cleared through our confidentiality memo series. And that again is in the course of their -- only in the course of their official duties.

Anyone else other than -- we -- I think we have a specific clearance for UPS personnel -- must get authorization to enter the security area from me.

Q What does UPS mean?

A United Parcel Service.

And he may not enter the area unless he's under the direct accompaniment of the supervising prescription clerk or the batch and edit clerk or a person I've designated to be in charge of that.

Q Is there a regular procedure setup for his arrival at that building?

A Yes.

I can't recall exactly whether he's making two visits -- two pickups a day or one. I think there is one in the morning and one in the afternoon.

Q He is picking up blank prescriptions? Is that what he is doing, is that it?

A That's correct, prescription blanks.

Q Being mailed out to doctors?

A Being sent out to practitioners.

Q This log, visitor's log that you referred to, where is that located?

A That's located in the office of the supervising prescription clerk.

Q Where is that individual located?

A That's behind the entry gate to our security area, that is, in front of the security fence.

Q But inside the room?

A But inside the room, yes.

Q Immediately inside?

A Her office is to left as you walk in, and adjacent to the security fence area, behind which the prescriptions are processed.

Q Have you written any memos or notices regarding access to these areas?

A Yes, sir, I have.

Q When?

A Back in March of 1974. I think there is a series of three memos, one to bureau employees, one to non-bureau employees, and then one in general with regard to access to the security area and the vault.

And there may be some others. Those are the main ones.

Q I show you a memorandum dated March 18, 1974. Is that the one to which you have reference?

A That's correct, sir. That's entitled "Access to the Vault and Security Area" and it's from me to all employees of our Bureau of Controlled Substances Licensing. It's dated March 18, 1974.

MR. FOGARTY: Mark it Defendant's Exhibit D for identification.

(Memorandum dated March 18, 1974 entitled "Access to the Vault and Security Area" from Joseph L. Cannizzaro to all employees of the Bureau of Controlled Substances Licensing, marked Defendant's Trial Exhibit D for identification as of this date.)

MR. LESCH: Let the record reflect that I object to Exhibit D on the ground that it is not included within the schedule of defendant's exhibits and constitutes unfair surprise.

MR. FOGARTY: Would you care for a recess?

MR. LESCH: At the conclusion of this deposition -- let me see how many more of these you pull out -- we'll make a determination.

Q I notice that this memorandum also contains signatures on an attachment.

A Yes, sir.

Q Are these the people who have access to the areas covered by the memorandum?

A That's correct, sir.

Q The same procedure is followed with regard to this as to the other clerks under your jurisdiction?

A This would be all of our Bureau of Controlled Substances employees.

Q This covers the bureau regulations with regard to the handling of these matters, is that correct?

A We also have a manual -- it's entitled "Security of Information from Unauthorized Disclosure" -- that will in essence encompass the substance of the confidentiality manuals and the access to security area and vault areas that have been previously mentioned here.

MR. LESCH: May we have that question and answer read back, please?

(Read question and answer.)

MR. LESCH: I move to strike the testimony beginning with the words "we also have the manual" on the ground that there is no such manual that has been offered in evidence or provided to us, and that any manual constitutes the best evidence of its contents.

Q Mr. Cannizzaro, I show you an undated document, and ask you if that is what you have just referred to.

A Yes, sir, it is.

Q Is this in effect an amalgamation or bringing together of all of the existing regulations with regard to the handling of triplicate prescriptions

as far as your bureau is concerned?

A Yes, sir, I believe it is.

Q What is the purpose of this?

A This is with regard to triplicate prescriptions.

Q Only with regard to triplicate prescriptions?

A Right.

Q These memos preceded it?

A Yes, sir.

MR. JAFFE: Objection.

Could you clarify for the record what that expression concerning preceded it means?

MR. FOGARTY: Yes, the memos that I am referring to are March 8th, March 11th and March 18th which are Defendant's Exhibits A, B and D.

MR. JAFFE: 1974?

MR. FOGARTY: Yes.

MR. LESCH: Off the record.

(Discussion off the record.)

MR. FOGARTY: Mark that Defendant's Exhibit E.

(Document headed "Bureau of Controlled Substances Licensing, Security of Information from Unauthorized Disclosure," marked

Defendant's Trial Exhibit E for identification as of this date.)

MR. LESCH: With Mr. Fogarty's permission, I would like to conduct a voir dire examination on Exhibit E.

VOIR DIRE EXAMINATION

BY MR. LESCH:

Q Who prepared Exhibit E, Mr. Cannizzaro?

A The copy that you are seeing there was prepared in the Office of Management Analysis.

Q Who in the Office of Management Analysis?

A I believe it's Mr. William Johnson.

Q When did he prepare it?

A I can't give you the exact date, but it was during November of 1974 when all of these procedures were consolidated into that one manual.

Q Was that in preparation for this trial?

A No, it was in preparation for our getting our manual in final shape, final as of that date, let's put it that way.

Q It's not in final shape now?

A As of that date. Because -- there will be, I'm sure, as we review it changes made.

Q As of what date, November, 1974?

A At -- November is when it was prepared,

sometime during the month of November of 1974. A lot of these things were consolidated into one and there were some additions made.

Q Has it been distributed to members of the Bureau of Controlled Substances Licensing?

A No, it has not.

BY MR. FOGARTY:

Q You say that a particular individual prepared this?

A In consultation with myself and with the office of the counsel and under review by the Associate Commissioner of Community Health Services.

The full physical preparation of the document was done by Mr. Johnson or his office.

Q It was not done on any particular day, was it?

A No, sir.

Q About how long did it take?

A Well, from beginning it's taken months, from the beginning. In fact, I think it was in preparation before I came with the Bureau.

Q Are your regulations with regard to the handling of triplicate prescriptions and the storing of them constantly being reviewed?

A Yes, sir.

MR. LESCH: I don't know if I have said this of record, but I also object to Exhibit E on the ground that it is not on the schedule of defendant's exhibits which the Attorney General's Office said it was going to offer in evidence in this case.

So far we have five exhibits, and none of them are on the schedule that was annexed to the pretrial order.

Q As I understand it, Mr. Cannizzaro, this is a vital on-going system which you are supervising?

A Yes, sir, it is.

Q Certain procedures are subject to change?

MR. LESCH: I object to leading the witness.

A Yes, sir, they are.

Q Do you, in fact, change any of the substance or basic purpose of what you are doing?

A No, sir, I do not. Our basic purpose is to maintain confidentiality of the prescription document data.

Q What would be the purpose of any refinements in your system or changes in your system?

A To make it even more secure than it is.

Q How would you become aware that such changes might be indicated or proper?

A It might be something that I might miss. It might be brought to our attention by other units of the department, or in consultation with other units of the department that are also involved with our documents, possibly through outside sources.

If anything comes to our attention that indicates that there is a need for improvement of our security, we will take steps to improve our security.

Q Going back again to the prescriptions themselves, once they go into the computer area, what product do you receive?

A On a monthly basis, we get a series of printouts which relate to the prescriptions that were processed during that particular month. We get these from the Office of Electronic Data Processing.

Q Is that automatic?

A Yes, sir.

Q What authorization, if any, underlies it?

A These were all developed initially under the authorization of Dr. Baker, the Associate Commissioner for Community Health Services.

Q What printouts do you receive?

A We get a series of statistical summaries with regard to the prescriptions that have been processed during the month.

We get one that relates -- identifies the NDC -- the drugs by NDC numbers, and gives us a breakdown as to the practitioner groups that are prescribing that particular item, the total number of those practitioners, the total quantity of the drug that was prescribed, the average per practitioner, total number of prescriptions and the average per prescription.

We get another printout that gives us a breakdown with regard to the total number of prescriptions that were processed during the month identifying -- breaking them down into those that were filled by pharmacies, those that were dispensed by practitioners, and giving us an overall total.

These will be broken down by practitioner group, the total number of prescriptions per practitioner group, number of practitioners prescribing and the average number of prescriptions per practitioner.

We get the same type of breakdown with regard to prescriptions that are being dispensed by practitioners, and then a separate breakdown for the

pharmacies showing the total number of prescriptions filled by pharmacies, the total number of pharmacies involved and the average number of Schedule II prescriptions per pharmacy.

We get another statistical breakdown that shows us the -- it's cumulative. It indicates to us the -- that -- based on the prescriptions that were processed in that given month -- it breaks those down into the numbers that were filled in any given month.

MR. LESCH: May I interrupt?

I excuse myself for doing so. But I know that we have offered exhibits in evidence which are the copies of the printouts that were furnished to us by the Department of Health, and I wonder if it would not be a little clearer for all of us if Mr. Cannizzaro could testify by reference to those exhibits. That is only a suggestion on my part. I'm not trying to try your case for you.

MR. FOGARTY: If the exhibits are here, I will give them to him, the printouts.

MR. LESCH: Are they any different from the printouts which we have already offered in evidence?

MR. FOGARTY: I suspect not, except that there might be updates. There might be later ones, that's all.

MR. LESCH: Rather than confuse the record, why don't you refer to the exhibits that have already been marked as plaintiffs' exhibits so that we don't have o sets. If they are the same exhibits --

MR. FOGARTY: They are the same information.

MR. LESCH: If they are the same basic information, rather than burden the record --

MR. FOGARTY: You were the one who asked for the updates and that's why we got them.

MR. JAFFE: The question is whether Mr. Cannizzaro's testimony --

MR. FOGARTY: I know what the question is. I am talking to Mr. Lesch.

MR. JAFFE: I am part of this.

MR. FOGARTY: I know you are, but I will get to you when I finish with Mr. Lesch. I am not going to talk to both of you

at once.

MR. LESCH: My only point is that there are trial exhibits which have already been marked at the request of plaintiff. If these are updates, they contain significantly different information, then by all means put them in. I might add that when I requested them, I did not expect to see them for the first time at trial. I expected to see them a reasonable time before trial. Apparently, this pretrial order was a one sided document, and that is the plaintiffs had to comply with it and the defendant didn't.

Off the record.

(Discussion off the record.)

BY MR. FOGARTY:

Q I show you Plaintiffs' Exhibits 13 through 21, both numbers inclusive, and ask you if these represent the printouts that you are receiving each month.

MR. LESCH: Is that at the present time?

MR. FOGARTY: The present time. Receiving is what I said.

A Three of these are in the format that we

are currently receiving them.

Q Which three of those?

A Shall I refer to them by the exhibit number here?

Q And the name, please.

A "Schedule II Substances Dispensed and Processed in Month of," and this one is February, and it's Exhibit No. 14.

The next one is "All Prescriptions Processed in Month of," and this is February, Exhibit No. 15.

"Report of Duplicate Prescriptions Processed in Month of February," and this is No. 16.

The next one which is a monthly printout has had a changed format.

MR. LESCH: Let the record reflect that Mr. Cannizzaro is now referring to Exhibit 18.

THE WITNESS: That is correct, sir.

Q What is the title of that exhibit?

A "Patients With Rx Total Dose In Excess 30 Day Supply In Month of February."

Q What is the change in that format?

A There are two primary changes.

No. 1, the patient identity as it exists in the computer is listed on this form, plus there is a spatial separation between the individual patient identities on the printout.

And there may be a change in the location of the column headings. But essentially the information is still the same.

Q In other words, it has not been changed in substance?

A No change in substance other than those items that I mentioned, the one item, patient identification.

MR. LESCH: I object to the "in other words" because I think this is a very substantial change.

Off the record.

(Discussion off the record.)

BY MR. FOGARTY:

Q Mr. Cannizzaro, I show you a copy of a printout and ask you if this is the update of Plaintiffs' Exhibit 18 to which you referred?

A Yes, sir, it is.

May I at this time comment that it does contain patient identities on here, and that I released

this to the office of the counsel with the direct approval of Dr. Baker for transmittal to the Attorney General's Office. And I'm wondering as to the appearance of the patient names on this document as to what --

MR. FOGARTY: I think we can stipulate as to the same thing we did with regard to patient names on the opening day of the trial that the names will not be revealed to anyone.

MR. LESCH: Yes.

May we have the exhibit that Mr. Cannizzaro is now reading from marked as Exhibit F so that the record is clear?

MR. FOGARTY: That stipulation will bind both lawyers and non-lawyers in this room.

(Update of Plaintiffs' Trial Exhibit 18, marked Defendant's Trial Exhibit F for identification as of this date.)

MR. FOGARTY: Off the record.

(Discussion off the record.)

BY MR. FOGARTY:

Q What is Plaintiffs' Exhibit 13? Would you describe it, please?

A It is entitled "Records Added To The Tape,

Practitioner Rx Transaction Record, Edit Error Listing, Asterisk Indicates Error."

And a second part to that is "Records Not Added To The Tape" under the same heading.

Q What exactly does that printout give you in the way of information?

A It indicates to me that of the prescriptions that have been processed through key punching there are a series of them that have errors on them that have been -- our criteria indicates that are not critical, and that those records have been added to the data processing tape file.

And the second one that was entitled "Records Not Added To The Tape," that those prescriptions have not been added to the tape file. The errors there according to our criteria are too serious for them to be entered into the tape record without an adequate follow-up.

Q The substance of this printout has not changed to the present time?

A No, sir, it has not.

These are daily records.

Q You get these every day?

A That is correct, sir.

And may I add at this time that we get one

additional daily record.

Q What is that?

A And that one is with regard to any prescription that is on our lost, stolen file that may have -- that has been filled.

Q You are referring to a prescription, a triplicate prescription which has been reported stolen --

A Right.

Q -- but has actually been cashed --

A That is correct, sir.

Q -- and forwarded to the Bureau --

A Right.

Q -- in accordance with that aspect of the law?

A That is correct.

Q And you get that listing every day?

A That is correct.

Q Do you have an exhibit before you that shows that printout?

A No, sir.

That is a new printout.

Q I show you a printout and ask you if this is a sample of what that lost prescription printout looks like.

A Yes, sir, this is itexactly. It's entitled

"Cashed Rx's Previously Reported Lost Or Stolen."

A When did you start making this printout?

A I think this started sometime in July of 1974 or thereabouts.

Q So that the one you have in your hand was produced when?

A This was received in our office November 20, 1974.

Q It has no prescriptions listed on it, though.

A That is correct, sir.

MR. LESCH: May we have this document that Mr. Cannizzaro is testifying about marked for identification so that the record is clear?

MR. FOGARTY: Yes, we will mark this Defendant's Exhibit G.

(Document headed "Cashed Rx's Previously Reported Lost Or Stolen," marked Defendant's Trial Exhibit G for identification as of this date.)

Q This, Mr. Cannizzaro, would actually be a refinement of Plaintiffs' -- what number are we talking about?

A Well, this is not a refinement. This is a new --

Q An addition to the edit error listing?

A Right.

Once we got the lost-stolen prescriptions into the computer file, we were able to generate this particular printout.

Q Would you refer, please, to Plaintiffs' Exhibit 14?

A Yes, sir, that's entitled "Alphabetic Listing of Practitioner Master File."

Q What exactly does that show?

A It gives the -- identifies the practitioners by their license number, profession code, BNDD number. It gives their purchase, prior purchase record and the order date of their prescription.

This relates to the sale of the prescription blanks and not to processing of prescriptions, of cashed prescriptions.

Q This then is a record of the prescriptions which you have sent to each doctor whose name appears on the document?

A Yes, this reflects -- this reflects the initial order record for each one of these practitioners.

Q In other words, each time he orders prescription blanks, his name will appear on this printout

sometime subsequent to the order?

A That is the way it will ultimately be, but at this time the -- this record reflects only the fact that he has had an initial order processed.

At a later -- the reorders are kept at this point on a manual basis with an adequate record, batch record made for the reorders, and they will ultimately be entered into the computer when that capability is realized.

MR. LESCH: Off the record.

(Discussion off the record.)

BY MR. FOGARTY:

Q Exhibit 14, printout entitled "Schedule II Substances Dispensed and Processed in Month of" -- it says February, but any month.

A There has been no change in that --

Q No change?

A -- printout, sir.

Q Exhibit 15?

A There has been no change in that printout.

Q That's all prescriptions processed --

A In the month of February, for this particular printout.

Q Exhibit 16?

A "Report of Duplicate Prescriptions Processed in Month of February."

There has been no change in the format of that printout.

Q Exhibit 17?

A Exhibit 17 is entitled "Unmatched BNDD Numbers." That we are not receiving at this time. We expect to resume the generation of this printout at a later date when it's feasible.

Q Why aren't you receiving it at the present time?

A We had a problem with it because all of the reorders were not in the computer file. When the reorders are placed in the computer file, we'll be able to make a better utilization of it.

Q Plaintiffs' Exhibit 18.

A I've testified to the changes in that, and I think --

Q There have been changes in format, not in substance, is that correct?

A There has been a change in the substance of it in the fact that the patient identity as it appears in the computer is indicated on the printout.

Q Exhibit 19?

MR. LESCH: The new printout is Defendant's Exhibit F, is that right?

THE WITNESS: Yes, sir.

Q Plaintiffs' Exhibit 19?

A There is no change in that format, sir.

Q Plaintiffs' Exhibit 20?

A No change in that format.

Q Plaintiffs' Exhibit 21?

A No change in that format.

Q There is only one of these printouts which contains a patient name, is that correct?

A That is correct, sir.

Q That would be Plaintiffs' Exhibit 18, is that correct?

A Yes, sir, the format and the substance of that has been changed.

Q That is as prescribed in Defendant's Exhibit F?

A That is correct.

Q What is the purpose of showing the patient's name on that?

A It identifies a patient who has received in excess of a 30 day supply of a Schedule II controlled substance, either from one or more than one practitioner.

Q What is the purpose for printing out this information?

A The law limits the supply that may be prescribed for an individual patient to a 30 day supply of a Schedule II controlled substance in this situation, and this enables us to identify those instances where we have patients who are receiving more than a 30 day supply from either one or more than one practitioner source.

Q Does it have any other use?

A Well, the data that is on the printout may not necessarily reflect -- may not necessarily mean that the patient as indicated on the printout is getting the indicated medication. There may be other possibilities involved that will only be disclosed by an investigative follow-up in some instances.

In other words, there may be some instances that it may be a practitioner -- even though it indicates it is a patient, it may be a practitioner that is obtaining medication possibly for his own personal use.

Q What other types of situations could be involved in the information supplied by this printout?

A In checking some of the entries there, that is, by going back to the original document in the file, the copy document that is in the file, and/or

checking against our lost-stolen list, we have found instances of forged prescriptions. That is, using this as the basic document.

Q Is there any other circumstance it might suggest?

A It also indicates here where a practitioner is prescribing more than a 30 day supply for any given patient, which would exceed the legal requirements.

Q Does it also identify the doctors?

A Yes, sir.

Q Or doctor from whom the patient has gotten a prescription?

A The printout identifies the patient, the doctor by BNDD number, the batch number location of the prescription, the serial number of the prescription, the NDC number of the drug, total quantity prescribed, the maximum daily dosage, the pharmacy where it was filled, the date prescribed, date filled.

Basically just about all of the data that's on the prescription document.

Q So that it might also show or indicate violations or possible violations by a doctor or by a pharmacist?

A That is possible, yes, sir.

Q That could be gleaned from this printout?

A I think only subject to, you know, a confirmation by either a file -- a review of the file documents or by investigation.

You may have situations wherein a particular pharmacy shows up repeatedly as filling certain types of prescriptions. I mean, there are a lot of things that can be gleaned from this, but they are -- what I am trying to say is that this information will ultimately have to be confirmed by an investigation.

Q With this information, the investigator is pointed to the areas of investigation, is that correct?

MR. LESCH: I did not hear that question, sir.

MR. FOGARTY: Would you read it back, please.

(Read question.)

MR. LESCH: I object to the question on the ground that it is leading.

A Yes, it does serve that purpose. We do make referrals to the Enforcement Unit for follow-up from this printout.

Q Who reviews this printout?

A I do, sir.

Q Anybody else?

A I review it and make assignments from it to the account clerk who I have trained to review the actual documents that verify the printout.

Q What do you mean by documents to verify --

A The prescription.

In other words, the prescriptions identified in the printout by batch number, and I had the actual prescription checked against the printout listing.

Q So that you and this clerk are the only ones who see this printout?

A It may also be seen by anybody else that I assign to do this particular operation. At this time, it's solely the account clerk or my principal clerk.

Q By this operation, you mean get the prescription itself?

A Right. View the prescription to verify the entry on the printout.

Q What do you do with that information when you get it?

A If it develops that it warrants what I consider investigative follow-up, a form memorandum is prepared identifying the patient and the pertinent data such as the practitioner BNDD number, the pharmacy BNDD

number, if it is involved, the name of the drug, and any other data that we may have obtained by internal checks such as the possibility it's a forged prescription, and refer that over to the Enforcement Unit for appropriate action on their part.

We also identify the practitioner and the pharmacy based on the BNDD number that appears on the printout and on the prescription document.

Q When you got a situation involving abuse of some sort or suggested abuse, could you get the information without this printout?

A Yes, sir.

Q How?

A By field investigation, that is, by going from pharmacy to pharmacy where you would get the data that relates to prescriptions that were filled by pharmacies, but you would not get any data from pharmacies in those situations where the doctor -- the practitioner directly dispensed medication to a patient.

Q If you were going as you say from pharmacy to pharmacy what in your experience would normally alert you to make such a canvass?

A The patient's name might be an indicator, a familiar alias that would be familiar to the

investigator, previously known.

Q How would the investigator --

A The -- pardon me.

Q Go ahead.

A The practitioner that was prescribing, that might be of interest.

The drug that was being prescribed.

There are many other factors, I mean, in the traditional method of going from pharmacy to pharmacy. Information from the pharmacies might be of some interest sometimes.

Q What would prompt you to go from pharmacy to pharmacy without the computer printout?

A Without the computer printout this would have been the traditional method of surveilling the prescription practices of the various practitioners, that would be to go to actual pharmacies that were filling the prescription and looking through them, and in that way trying to determine if there were any situations that might need correction of deficiency or investigative follow-up to determine -- particularly where a violation of the law might be suspected.

Q I believe you said there are 26 narcotic investigators in the State of New York.

A I believe about 24, sir.

Q Could 24 investigators cover every pharmacy in the State?

A Can they?

Yes, they can, but I think it would take -- take quite a long time. It might go into years.

Q How does this printout affect your operation?

A I believe that it offers a centralized opportunity to have all of this data compiled, processed and furnish an indication of where there would be situations that should be subjected to investigation.

Q What would be the value of this printout without the patient's name?

MR. LESCH: Are we still referring to Exhibit F?

MR. FOGARTY: Yes, we are.

A It would make it very difficult to utilize.

One of my original referrals was made from a printout during -- not furnishing the patient identity. I testified to this previously, where the investigator subsequently advised me that in that particular instance, the matter had already been investigated, and that it had been wasteful, in fact, duplicated, where I had not furnished the patient identity to the investigator.

Q Then the information contained in this printout without the patient name is of little value?

MR. JAFFE: Objection.

That was not his testimony.

MR. LESCH: I object to that, too.

MR. JAFFE: It is leading.

MR. LESCH: You are trying to lead the witness on one of the most important questions in the case. I would astounded if he were to say that incidentally.

A It's of lesser value.

Q Basically it gets you back to the old system, doesn't it?

MR. LESCH: I object to that questionon the same grounds.

A It makes it less useful.

Q That is the only printout that contains the name of the patient?

A We have a -- another printout that we are utilizing now that will contain -- does contain the patient identity and this is in those instances where the investigative unit, the Enforcement Unit requests a specific printout for a particular or specific subject which is under -- which may be under investigation.

For example, it may be for a specific physician, specific patient, specific pharmacy or specific drug. And we are furnishing in response to that type of request a printout which will give the complete prescription history of the doctor, patient, and/or pharmacy, or where a specific drug is selected a specific drug history.

Those all contain patient identities, the doctors by BNDD number, pharmacies by BND number, NDC number of drugs, and the other data which relates to the NDC number of the drug, the quantity, maximum daily dosage and dates.

Q But that is not a regular printout?

A No, sir, that is not a regular printout.

Q Has there been any implimentation of the sections of this statute referring to the length of time that this information will be kept?

A Yes, sir.

We have developed a manual of procedure for the purging of the -- actually the destruction of prescriptions that reach an age of approximately four years, 11 months, so that we comply with the new statutory requirement in that area that prescription records containing patient identities in essence be

destroyed within five years of the date of issue -- of the date that the department has received a record.

Q What has been done in that regard?

A We have established a policy and procedure with that, with the necessary records to reflect the destruction of the prescriptions. And that will be implemented, I believe it's May of 1978.

Q What will be done at that time?

A The prescriptions will be withdrawn from the vault and shredded in our security area under adequate supervision with an appropriate record of the destruction being made.

And this will be done on a monthly basis.

Q What kind of a record will be kept?

A It will be a log showing the date of destruction, the batch numbers, beginning and ending for that particular destruction, together with the calendar dates of the batches involved, the signature of the supervising prescription clerk and the principal clerk who will actually conduct the destruction by shredding with our own shredder within our security area.

Q This will relate to the prescriptions themselves?

A That is correct, sir.

Q From the log that you are preparing, will it be possible to determine, let's say, the identity of any patient whose prescriptions have been destroyed?

A No, sir.

Q Any doctor who wrote those prescriptions?

A No, sir.

Q The pharmacy that filled them?

A No, sir.

Q The doctor who dispensed them, if he's a dispensing physician?

A No, sir.

Q In other words, there will be no record?

A None.

Q This plan takes effect when?

A I believe it's May 1st of 1978.

Q Is this the plan to which you have reference?

A Yes, sir, it is.

Q When was that prepared?

A This was prepared during the month of November of 1974 by the Office of Management Analysis, after consultation with myself, the office of the counsel, Mr. Ambrose Donovan, and reviewed by Dr. Baker, the Associate Commissioner of Community Health Services, and I believe there was some consultation and review with the

Office of Management Analysis -- Office of Electronic Data Processing.

I think the date of inception will be March 1, 1978. I previously testified in error to it being May 1, 1978.

MR. FOGARTY: Mark this Defendant's Exhibit H.

(Document headed "Bureau of Controlled Substances Licensing, Triplicate Prescriptions Record Retention, Purging of Prescription Files," marked Defendant's Trial Exhibit H for identification as of this date.)

MR. FOGARTY: No further questions.

MR. LESCH: I object to Exhibit H on the same grounds that I have objected to the other exhibits of defendant, namely, that they are not included on the list of exhibits which was furnished to us by defendant's counsel and is annexed to the pretrial order.

Maybe we should take a recess at this time.

MR. FOGARTY: Fine. How long?

MR. LESCH: Ten minutes, five minutes.

MR. FOGARTY: All right.

(Short recess.)

(Whereupon, at 12:15 p.m., a luncheon recess was taken.)

oOo

AFTERNOON SESSION

1:50 p.m.

J O S E P H L. C A N N I Z Z A R O, resumed the stand and testified further as follows:

EXAMINATION BY MR. LESCH:

Q Mr. Cannizzaro, are you able to describe the manner in which the Bureau of Narcotic Control would follow-up an investigation with respect to a patient who is going to one or more practitioners in order to obtain an excess of the 30 day supply of the Schedule II controlled substance?

A No, I don't believe that I can describe their current procedural practice in that area.

Q So that you really don't know what the Bureau of Narcotic Control does with any information that you may give to the Bureau of Narcotic Control, is that correct?

A Substantially so.

You mean specifically with regard to any item that I would send over to them, refer for appropriate action for an investigator to follow, I would not know the specific mechanics of what they do in each specific individual situation.

Q You are not familiar with the investigative techniques that they are currently following in order to apprehend violators of Article 33, is that correct?

A I think my answer would have to be that I'm not familiar with what they actually do at this particular time, but I do not think that it would deviate much from prior practices as far as the follow-up of any prescriptions that might have been viewed within the files of pharmacies in the past. Or as occurs currently.

Q You recall, do you not, sir, that when I asked you this question at your deposition in this case on April 24th of this year, you responded that you did not know the method by which your reports are followed up, isn't that right?

A I did state that, yes, sir.

Q You said to me that if I wanted to know the way that the investigations were followed up, I should discuss that with Mr. Bellizzi.

A Yes, I think I described him as the best source of information in that area as relating to their current procedures.

Q You said that you really couldn't tell how they were going to follow it up, didn't you?

A Substantially, yes.

Q Yet, you are the person who decides what information is sent to the Bureau of Narcotic Control, isn't that right?

A From our triplicate prescriptions, yes, I am.

Q You also testified this morning that beginning in or about August of this year, you have established a printout which contains patient names, is that right, sir?

A I don't know whether I made a specific reference to the date.

Q What is your best recollection right now as to the date when a printout containing patient names was first established by you?

A My recollection is that it was prior to August of this year.

Q Was it in July?

A Very possible.

Q Is that your best recollection now, that it was in July that a printout --

A No, it's not my best recollection.

Q What is your best recollection?

A That it was sometime subsequent to April of this year.

Q Can you be more precise than that?

A Not without reference to my records.

Q Are those records here with you today?

A No, sir, they are not.

Q Exhibit F is a printout of patient names, is it not, sir?

A It incorporates patient names as one of the data items as identified in the computer.

Q Weren't you told that it was the policy of the Department of Health not to prepare printouts containing patient names?

A No, sir, I was not.

Q Are you familiar with the report that was prepared by Chester R. Hart, who was chairman of the Temporary State Commission of the State of New York to evaluate the drug laws?

A Which report is that, sir?

Q It is Exhibit 33 in this case.

Are you familiar with that?

A May I see it, please?

Q Yes.

A I'm not familiar with that.

Q Would it surprise you, sir, to learn that Assemblyman Hart at the time that Article 33 was presented to the Legislature stated that the proposed plan will not make use of massive printout of patient names?

A No, sir, that statement would not surprise me.

Q Would it surprise you to learn that Assemblyman Hart also said that the computer will not disclose identifying data about any patient unless based upon previous reports it is clear that such patient has been using stolen or forged prescriptions?

A No, I'm not surprised.

Q That does not surprise you?

A No, sir.

Q Isn't it a fact, sir, that Defendant's Exhibit F is a printout of the names of a large number of patients about whom there is no prior information or indication that those patients have been using stolen or forged prescriptions?

A There may or may not be prior information.

I can't tell just by looking at that particular printout, that one sheet that we have here.

Q But you testified this morning, Mr. Cannizzaro, that you made a decision to have a printout of patients with a total dose in excess of 30 days supply.

A That's correct, sir.

Q Isn't that right?

A That's correct.

Q You are not suggesting, are you, that every patient who received in excess of 30 days supply that you had a report about such a patient that he had been using a stolen or forged prescription, are you?

A No, sir, I'm not suggesting that.

Q So we have it then that Exhibit F is a printout that discloses identifying data about patient, isn't that right?

A That's correct, sir.

Q We also have it that the patients who are disclosed on Exhibit F are not patients about whom you have had any reports that they have used stolen or forged prescriptions, isn't that correct?

MR. FOGARTY: Objection.

A I've already answered that question previously. We may have some prior information. I don't

know.

Q I would like to know what the prior information is about any of the persons who are listed on Exhibit F that they used a stolen or forged prescription.

A I would have to check our files to see if we have any prior printout, for example, or a memorandum indicating that there was some material that would relate to that particular patient or identity on that prescription -- on that printout.

Q About how many persons are listed on the full printout of which Exhibit F is the first page?

A I don't know.

Q How many pages is the printout of which Exhibit F is the first page?

A I don't know that accurately, but I would estimate that it approximates 100 sheets.

Q Are you suggesting, Mr. Cannizzaro, that there is a report within the State Department of Health about every person listed on those 100 sheets that they have utilized a stolen or forged prescription?

A No, sir, I'm not suggesting that.

Q There are a number of persons who are listed on that printout about whom there is no report

that they used a stolen or forged prescription, isn't that right?

A That could be right. Could be.

Q Because the manner in which the printout of which Exhibit F is the first page is compiled is that the sole criteria that is given to the computer is whether or not they have received prescriptions in excess of a 30 day supply, correct?

A I believe that's part of it.

Q When you say that is part of it, what have I left out?

A That only -- those instances where the quantity exceeds a 30 day supply, but also those instances where there is a multiple source of the prescriptions. In other words, where the patient, in effect, is obtaining controlled substances from more than one physician which would be indicative of a patient shopping from one physician to another.

Q That is correct, but in instances of those patients, the total supply that the patient has obtained would have to be in excess of a 30 day supply, isn't that right?

A No, sir, that's not correct.

Q Will you explain to me why that isn't

correct? Because as I read it, the title of Exhibit F is "Patients With Prescription Total Dose in Excess of 30 Days Supply Processed in Month of August."

A Right, that is the title. But in modifying the format, we also built into it, without modifying the title of the printout, the situation that I described where a patient that is obtaining medication from more than one physician is also identified in this particular printout.

Q So there are patients on the printout who receive less than the 30 days supply, but receive the same drug from more than one physician, is that your testimony?

A Not necessarily the same drug, but it would be a Schedule II controlled substance.

Q Any Schedule II drug from more than one physician, whether or not it exceeds a 30 day supply?

A That is correct, sir.

Q Limiting ourselves for the moment to those patients who are shown on the printout of which Exhibit F is the first page to have received more than a 30 day supply in any month, is it not a fact, sir, that there is no information in the Department of Health that indicates that those patients had been using stolen or

forged prescriptions?

A There may be.

Q Would there be such information with respect to every such patient?

A In checking this particular printout, we have run into situations where a prescritpion listed on a printout is a lost, stolen or forged prescription.

Q I have no doubt about that, but my question to you is whether every person on that printout who is shown to have received more than a 30 day supply is also shown by comparison with another one of your printouts to have been using a stolen or forged prescription.

A Every patient?

I would say no.

Q Thank you. That is all I was trying to establish. To the extent that Assemblyman Hart said in Exhibit 33, "The computer will not disclose identifying data about any patient unless, based upon previous reports, it is clear that such patient has been using stolen or forged prescriptions," to the extent that he said that he was in error, was he not?

A I don't know, sir.

Q Does that statement seem to be correct to you after the testimony that you have just given?

A Well, I -- you know, I really don't know what his statement means.

Q You don't understand the statement?

A No, not completely.

Q What about the statement don't you understand?

A I don't know what -- just exactly what his statement means. If you want to read it again, I'll try to give you my reason for not being able to make this comparison that you wanted me to make.

Q Rather than my reading it again, why don't you read it to yourself. It appears at Page 4 of Exhibit 33. It is the last sentence on the page.

A I don't know actually what -- when he makes that statement or when he made that statement, if that's a complete statement.

Q I am not asking you whether it is a complete statement. I am asking you whether in light of the present practices of the Department that you have now testified to the statement which is shown as the last sentnece on Page 4 of Exhibit 33 is in error.

A I would not say that it's in error.

Q Didn't you just tell me that there are printouts such as Exhibit I which contain the names of

patients about whom the Department has no indication that they were using stolen or forged prescriptions?

A That's correct, sir. I can't tell until these things are checked.

Q Doesn't Assemblyman Hart --

MR. FOGARTY: Objection. He answered the question five different times and he said the same thing each time.

MR. LESCH: Are you directing the witness not to answer?

MR. FOGARTY: No. Do you have any objection to my making an objection?

MR. LESCH: You can make as many objections as you like.

MR. FOGARTY: Fine.

Q Doesn't Assemblyman Hart say to your understanding that printouts will not be made of patients unless the Department has an indication that they were using stolen or forged prescriptions?

A That's the statement that's in that letter. I don't know what his complete statement would be with regard to this whole area that we're discussing.

Q Why don't you assume with me for the moment that I am not trying to mislead you and that

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this statement is correct, and if it turns out that there is something that is to be added, I am sure your counsel will add it on redirect.

Turning again to the last sentnece on Page 4 of Exhibit 33, is it or is it not in error in light of the present practices of the Department of Health?

A I would not characterize it as being in error. I still won't characterize it as being in error.

Q How would you characterize it? Would you characterize it as being correct?

A There is a difference. There is a difference, but I won't say that he was in error or is in error.

Q Would you say that it does not accurately set forth the policy of the Department of Health with respect to computer printouts?

A I think I described what we're doing and his statement in his letter speaks for himself.

And if you want to draw any difference, I think you can. I can see that there is difference, but if you are saying that he is in error, I don't believe that I can make that judgment just by looking at that statement.

Q Sir, in addition to Exhibit F, you testified

that there are additional printouts that are now being prepared by the State of New York with respect to patients, is that correct?

A Yes, sir.

Q Those additional printouts are printouts that contain data with respect to individual patient that have been requested by the Bureau of Narcotic Control, is that correct?

A That's correct, sir.

Q Such printouts include, for example, all Schedule II drugs that have been received by a particular patient, is that correct?

A That's correct, sir.

Q How many such printouts have been turned over by the Bureau of Controlled Substances Licensing and Evaluation to the Bureau of Narcotic Control?

A I would estimate at this point about five or six.

Q When were they turned over?

A I think beginning sometime in the latter part of September or early October.

Q Are you familiar with the pretrial order on consent that was entered into between the parties in this case?

A I have not read this, sir.

Q I direct your attention to Paragraph 13 which starts at Page 7 and begins, "As presently in effect, the following printouts are produced by the State system..." Then I direct your attention to the list of printouts that follows, and particularly F, which is Subparagraph (f) "Patients with prescription total in excess of a 30 day supply processed in month ..." and that is the printout which is now known in our case as Exhibit F, isn't that correct, sir?

A That's correct.

Q Then there are additional number of printouts listed, and then in Paragraph 15 it says:

"The only printout which contains patient names is that described in 13(f) above."

Do you see where it says that, Mr. Cannizzaro?

A Yes, I do.

Q Are you now saying that that statement was erroneous?

A No, sir, I'm not saying that.

Q Didn't you just tell me a moment ago that there is another printout that contains patient names?

A Yes, sir. But those are not regularly received. Those are only in response to a specific request.

Q You have never seen the pretrial order before today?

A No.

Q It has not been discussed with you by anyone?

A The contents of it may have been discussed with me. I'm not aware that it was specifically identified as the contents of that particular order or document that you have in front of you.

Q You mentioned a number of uses for Exhibit F on your direct examination. Do you remember that?

A Yes, sir.

Q Have there been any prosecutions whatsoever based on the information that has been contained on the printout entitled "Patients With Prescription Total Dose In Excess of 30 Day Supply Processed in Month of," since that printout was issued by the Bureau of Controlled Substances Licensing & Evaluation?

MR. FOGARTY: Objection.

A I don't know, sir.

Q So you don't know whether that Exhibit F has been of any use to the Department of Health whatsoever,

do you?

A Yes, I do know that there has been some use made of it because I use it myself to make extracts of data from this document and referred it over for investigative follow-up by the Bureau of Narcotic Enforcement.

Q But you don't know what the investigative follow-up has been, do you?

A Well, I don't know what the subsequent use -- the final results are or have been.

Q So as far as you know, there hasn't been any use whatever made --

A I just described the use that has been made by my Department as far as I know.

Q That is the full extent of your knowledge?

A That is correct.

Q You have no knowledge of any prosecution of individuals listed on any edition of Exhibit F, do you?

A Not at this point in time.

Q You have no knowledge of any arrests made of any individuals listed on the printout called "Patients With Total Dose In Excess of 30 Day Supply Processed In" a particular month, do you?

MR. FOGARTY: Objection.

A No, sir.

Q You have no knowledge of any case reports of violations of any patient listed on this printout, Exhibit F, do you?

MR. FOGARTY: Objection.

A No, sir.

Q Mr. Cannizzaro, I show you Exhibit C in this case. You saw that this morning, did you not, when it was shown to you by Mr. Fogarty?

A Yes, sir.

Q Do you recall that Mr. Fogarty asked you whether you were familiar with Exhibit C?

A He may have.

Q You don't recall that right now, is that right?

A I think I said he may have. I know I looked at it. I don't know if he specifically asked me that question as to whether I was familiar with it or not.

Q Do you recall when Mr. Fogarty showed you Exhibit C, you said you may have seen the document, but you are not familiar with it.

MR. FOGARTY: Objection.

That's not the question he answered that way. What I showed him was a different exhibit and I did not put it in evidence.

MR. LESCH: I think the record will speak for itself on this.

MR. FOGARTY: I hope it will.

Q Mr. Cannizzaro, will you answer the question, please?

A I would actually like to have read back to me that particular question that you are alluding to by Mr. Fogarty to me concerning this document.

MR. LESCH: We'll see if we can accommodate you.

(Record read.)

MR. LESCH: May we have the document that was referred to at that point?

MR. FOGARTY: For what purpose?

MR. LESCH: For my cross-examination of the witness.

MR. FOGARTY: There is no testimony as to it.

MR. LESCH: Let the record reflect that we have just gone back to the point in the testimony this morning that I was referring to and the question as read by Mr. Blitz refers to a document entitled "Administrative Policies, Procedures and

Forms, Office Practice" dated in March of 1973, and I am now asking Mr. Fogarty for that document with respect to which he asked Mr. Cannizzaro a question.

MR. FOGARTY: Which was never answered.

Now what do you want the document for?

MR. LESCH: The question was answered. Listen to the answer.

Mr. Blitz, would you read back the witness' answer?

(Record read.)

MR. LESCH: That is the document that I would like to have.

MR. FOGARTY: You have it.

MR. LESCH: Which document is it?

MR. FOGARTY: It's in the group I gave you this morning.

MR. LESCH: May we have this document marked as Plaintiffs' Exhibit 42 for identification.

(Document dated March 22, 1973 on the letterhead of The State Commissioner of Health, Albany, New York, marked Plaintiffs' Trial Exhibit 42 for identification as of this date.)

Q Mr. Cannizzaro, did you hear the question and answer that Mr. Blitz just read back with respect to what has just been marked Plaintiffs' Exhibit 42 for identification?

A No.

MR. LESCH: In that case, I would request that Mr. Blitz read it back again.

(Read question and answer.)

Q Is it correct then, sir, that you have seen Plaintiffs' Exhibit 42, but you are not familiar with it?

A That's correct, sir.

Q Is it also correct, sir, that Plaintiffs' Exhibit 42 was the document that set forth the policies of the Department of Health with respect to confidential information until it was superceded on February 27, 1974 by what is now Exhibit C in this case?

A I don't believe that this Exhibit C is a superceding document. This is an entirely different document.

Q Let me see if I can help you out.

I show you Exhibit A in this case, and I direct your attention to the first sentence of the second paragraph of Exhibit A which reads:

"Attached is a copy of G. A. Manual, Item 83 (updated 2/27/74)."

I ask you whether by looking at Exhibit A in this case you are now able to tell me whether Exhibit C did not supercede Plaintiffs' Exhibit 42.

A Plaintiffs' Exhibit C is Item 83 of the GA Manual, and it was an attachment to my memo of March 8, 1974.

This other document that you are referring to --

Q Referring to Plaintiffs' Exhibit 42.

A -- Plaintiffs' Exhibit 42 is Item 83.1 which is an entirely different document.

Q So that you are not at all familiar with Item 83.1, is that correct?

A I said I've seen it. I'm not completely familiar with it. It relates to electronic data processing and their confidentiality and security procedures.

Q You are not familiar with the --

A Not toally.

Q -- procedures for confidentiality of OEDP?

A I said not totally.

Q Don't you consider it part of your responsibility to make sure that the information that is

computerized is also kept confidential?

A I'm concerned, yes.

Q Don't you think that it would have been appropriate for you as the head of the Bureau of Controlled Substances Licensing & Evaluation to familiarize yourself with the confidentiality procedures of OEDP?

MR. FOGARTY: Objection.

A As I've indicated, I am in a general way conversant with their security procedures, but not specifically because it is a direct responsibility of the Director of the Office of Electronic Data Processing to provide for that type of security. I'm not familiar with their data processing system and the types of record formats and procedures and devices that they utilize.

Q Do you have any training in the area of maintaining the confidentiality of records, sir?

A I think about 27 years worth.

Q You consider all of your investigations as an investigator for the Bureau of Narcotic Control training in the area of maintaining confidentiality of records?

A Part of my activities were definitely related to maintaining confidentiality, because that

was a statutory requirement.

Q All you are saying is that you as an investigator had been told not to divulge any information that came into your possession by virtue of your office to unauthorized personnel, isn't that right?

A No, I also practice in addition to being told and being instructed, I also practice the maintenance of confidentiality, preservation of documentary and other types of evidence and material.

Q But you never drew up a set of guidelines for a large number of people to follow with respect to the maintaining of confidential information, did you?

A No, I did not do that.

Q You never consulted with anyone who was expert in that field in connection with assuring that a large number of persons did maintain the confidentiality of those records, did you?

A That's a hard question to answer.

Q Why don't you do your best.

A Pardon me. Yes, I'm going to try to do my best, Mr. Leech.

Over the years, I've had many instances where the preservation of evidence has been discussed, has been the subject material of courses which I have

taken, both given by the Civil Service Department and the -- at that time the Federal Bureau of Narcotics.

And in the course of many prosecutions and investigations in discussion with District Attorneys, for example, where we were always vitally concerned with the protection of any evidence material, including prescriptions --

Q Yes, but, Mr. Cannizzaro, my question to you was whether you ever consulted with any expert in the field of maintaining confidentiality with respect to drawing up a set of guidelines.

A Well, the difficulty is that many of those people, I'm sure, were experts, although they might not have been labeled as an expert in the field of maintaining -- developing guidelines for maintaining confidentiality.

Q Yes, and that is my question to you.

Did you discuss drawing up --

A I may have. My answer is that I may have.

Q Do you have any recollection of any individual with whom you discussed that?

A Specifically, no.

Q Are you responsible for the maintaining of the confidentiality of the printouts that come to

you from OEDP?

A Yes, sir, I am.

Q Is there a set of guidelines or procedures with respect to maintaining that confidentiality?

A Yes, sir.

Q Has that been marked for identification today?

A Yes, sir, I believe that's the document that's entitled "Security of Information From Unauthorized Disclosures."

Q Will you show me the exhibit to which you have reference?

A I believe that's Exhibit E.

Q Where in Exhibit E, Mr. Cannizzaro, is the regulation that describes the manner in which you are to maintain the confidentiality of the printouts that you receive from OEDP?

A They are not described specifically in this particular document.

Q Is there any document that has been marked for identification that does describe the regulations pursuant to which you are to maintain confidentiality of the printouts which you received from OEDP?

A The printouts that this relates to are the

printouts that I described earlier where a specific request is received from the Bureau of Narcotic Enforcement which would relate to a specific patient, practitioner, pharmacy or drug. That is the procedure and it's outlined in here indicating how it's to be processed by us, approved by the Associate Commissioner of Community Health Services, and then, in turn, delivered to the Bureau of -- the Office of Electronic Data Processing for preparation of the requested printout, and then, in turn, delivery to the requester.

Q So we have it then that there is no procedure that has been established pursuant to which Mr. Cannizzaro, namely yourself, maintains the confidentiality of printouts that are received from OEDP, is that correct?

A The procedure is also incorporated right here. I'm also one of the people subject to Section 33.71 of the Public Health Law.

I can't disclose any information contained on the prescriptions unless it's in the course of my official duties.

Q So that all of the rules and regulations which have been passed or have been promulgated by the Department of Health are simply Section 33.71, but there

have been no regulations which implement 33.71 with respect to you, Mr. Cannizzaro, maintaining confidentiality of printouts that you receive from OEDP?

A You mean specifically by name?

Q Yes, sir.

A I have never seen one to that effect.

Q How about specifically by office?

A I'm charged with the overall responsibility for the administration and supervision of that office by -- under the direct supervision of the Associate Commissioner of Community Health Services. I have not seen a specific document as you are indicating should be in existence.

A There is no document that describes the procedures that you are to follow when you receive printouts from OEDP, is that correct?

A There is as I have indicated in this security manual --

Q Exhibit E?

A Right.

Q Wherein Exhibit E is that set forth.

A With specific reference to the items that I just alluded to, that is, handling the specific requests from the Bureau of Narcotic Enforcement that would relate to patient identity.

Q Yes, but I am not talking about only those specific requests, Mr. Cannizzaro. I am talking about all of the printouts that you receive from OEDP.

I ask you again whether there is any written regulation that you are aware of which describes the procedures that you are supposed to follow with respect to maintaining the confidentiality of those printouts.

A Item 83 applies to me. Section 33.71 applies to me.

I am charged with the overall responsibility for operating that bureau and maintaining confidentiality.

Q Is there anything in Item 83 that says what you are supposed to do --

A Me specifically?

Q -- when you receive a printout -- you or anyone else who receives a printout from OEDP?

A No.

Q Is there anything in Item 83 or any other document that has been prepared by the Department of Health which says how many copies of a printout you may receive from OEDP?

A No.

Q Is there any regulation that has been promulgated which says when documents or printouts that have been received by you from OEDP are to be destroyed?

A Definitely in the situation of the specific request as outlined in this particular security manual, Exhibit E.

Q Mr. Cannizzaro, just so that we don't have to keep repeating ourselves here, I am not limiting my question to specific requests of the Bureau of Narcotic Control is making of you.

I am asking you with respect to all of the printouts that are received by you and anyone else in the Bureau of Controlled Substances Licensing & Evaluation, are there any procedures which set forth when those printouts are to be destroyed.

A Written procedures you are asking?

Q Yes, sir.

A No, sir. Not to my knowledge.

Q Are there any procedures which say whether or not you or anyone else who receives a printout from OEDP may take them off the premises of the Department of Health?

THE WITNESS: Let me have that question again, please.

MR. LESCH: Mr. Blitz.

(Read question.)

A The only specific ones again relate to the -- those selected request printouts.

Q So there is no procedure --

A No written procedure.

Q There is no written procedure, Mr. Cannizzaro, which describes when the printout that contains the list of all patients who have received in excess of a 30 day supply of Schedule II drugs may be taken from the premises of the Department of Health, is that correct?

A There is no written procedure.

Q Is there any written procedure as to whether anybody who receives such a printout from OEDP may make Xerox copies of it?

A There is no written procedure relating to that.

Q Is there any provision that you or anyone else who receives printouts such as Exhibit F from OEDP receive such prints that you have to sign a slip for them indicating that you have received the printouts?

A Did you except the items in Exhibit F?

Q I am referring to Exhibit F.

A Yes.

Q When you receive Exhibit F, do you have to sign anything indicating that you have received it?

A Which one is Exhibit F?

Q Here it is.

A This Exhibit F, this is the patients with Rx doses in excess of 30 day supply processed in the month of August. When this printout is ready or was ready Data Processing notifies my print clerk, it's delivered to her and she logs it in.

Q The clerk logs it in?

A That's right.

Q Then the clerk gives it to you?

A That's correct.

Q Where is the procedure, the written procedure pursuant to which the clerk logs it in?

A There is no written procedure.

Q Is there any procedure pursuant to which you have to sign a receipt that you have received Exhibit F?

A No, sir.

Q Mr. Cannizzaro, after you have received Exhibit F, you make a determination as to certain names on Exhibit F that are to be given to the Bureau of

Narcotic Controls for further investigation, is that right?

A I make a -- I scan it, and will make a determination as to which of the items should be ultimately referred over to the Bureau of Narcotic Enforcement.

Q Have you, in fact, referred various items on Exhibit F over to the Bureau of Narcotic Control?

A Yes, sir.

Q Do you receive a written receipt from the Bureau of Narcotic Control whenever you turn such items over to them?

A All I turn over to them is a memorandum identifying the particular, let's say, patient subject on that particular report and pertinent data which we will translate in some instances, for example, the BNDD numbers, will translate those into the actual practitioner identities and pharmacy identities and the NDC numbers, drug identities.

Q Do you receive a receipt when you turn over that type of memorandum to the Bureau of Narcotic Control?

A No, sir, I do not receive a receipt.

Q How does it get to the Bureau of Narcotic Control?

A It's -- those memos are delivered by my secretary or one of the clerks in my office in her absence directly to the Bureau of Narcotic Controls.

Q Is the Bureau of Narcotic Controls in the same building?

A The same building.

Q Are there any security guards in the building where your offices are?

A No, sir. Not to my knowledge.

Q Are you aware of any security precautions that are taken at night after you leave the premises?

A Yes, sir.

Q Are those precautions set forth in writing anywhere?

A Yes, sir.

Q Where are they set forth?

A I believe you may have them in here with regard to the closing and locking of our offices and the turning on of the central station alarm both for our security area and for the vault.

Q Will you show me by reference to defendant's exhibit in this case what you have reference to?

A I said they may be in here. I'm not sure

that they are.

I don't believe it's in here. I was looking at the access to vault security area memo of March 18, 1974. It's not included in there, but we have it documented.

Q Mr. Cannizzaro, are you bound by the strictures contained in Defendant's Exhibit B and D for identification?

A I don't understand your question as to whether I am bound by the strictures.

Q Are you also supposed to follow the instructions that are contained in Exhibits B and D?

A I run the Bureau. I see that those instructions are adhered to by my employees in the Bureau.

Q Are you also supposed to follow those instructions?

A Well, which ones do you have reference to? Let's be specific.

Q I am talking about all of the material in writing --

A I set those up.

Q I am asking you whether you follow them also.

A Where I am identified in here, I, of course,

adhere to those portions of it. Where it says the director does this, the director does that, he does that.

Q I don't see that the director is mentioned at any place in Exhibit B. Does that mean that you feel that you are entitled to disregard Exhibit B?

A Absolutely not.

Q That is what I am asking you.

You feel bound by Exhibit B, don't you?

A I have to adhere to Item 83 of the GA Manual. However, this memo is from me to all employees of the Bureau of Controlled Substances Licensing. They are complying with my memo that I prepared. I, of course, comply with Item 83 myself.

Q Your signature does not appear on the signature sheets that are attached to Exhibit B, is that correct?

A That's correct, sir.

Q Your signature does not appear on the attachment to Exhibit D either, is that correct?

A It doesn't appear on the attachments to either one of those, but as I explained to you that memo is from me. I've signed it, both of them. Those are my directives.

Q Similarly your signature does not appear

on Exhibit A, is that correct?

A It appears on Exhibit A as being from me to all non-bureau employees, Bureau of Controlled Substances. Again, that's my directive as far as the confidentiality of records.

Q What investigation is made of non-bureau employees of the Bureau of Controlled Substances Licensing before they are permitted access to the Schedule II information?

A You have reference now to this memorandum here and the people identified, non-bureau?

Q Yes, sir.

A Okay.

Now these --

MR. LESCH: Let the record reflect that Mr. Cannizzaro is referring to Exhibit A.

THE WITNESS: Exhibit A. And the people identified there are all State Health Department employees.

Dr. Baker who is the Associate Commissioner of Community Health Services.

Frank Conte who is no longer an employee of the State Health Department. So

he has been updated. On our new list, he is deleted.

Mrs. Cook, Office of Electronic Data Processing.

Mr. Ovedovitz, Mrs. Yemmo, Mr. Kevin Brennan, also from the Data Processing Office.

And Mr. William Aumic, the administrative assistant to Dr. Baker.

Those are subjected to the usual civil service type of clearance.

Q Is a drug check made by the civil service when it is checking potential employees of the Bureau of Narcotic Controls or the Bureau of Controlled Substances Licensing & Evaluation?

A As I testified earlier today, I'm not totally aware of the civil service investigative procedure. I do know that they have an investigative unit. I assume that drug utilization would probably be one of their items. Now I don't know.

Q Is it also correct that you don't know whether a check is made to determine whether any of the persons under your supervision have criminal records?

A All I know is that they are subjected to the usual civil service clearance procedures, whatever

those are. As I indicated to you, I'm not aware of what they are.

Q So is it also correct, Mr. Cannizzaro, that you do not know whether any of the employees under your supervision have criminal records?

MR. FOGARTY: Objection.

The question has been answered.

A I think I've answered that question.

MR. LESCH: Are you instructing the witness not to answer?

MR. FOGARTY: I merely stated an objection.

THE WITNESS: I think I've answered that question adequately, that --

MR. LESCH: With all respect, I don't think it is your decision to make whether the answer is adequate or not.

Q I would like to know whether you know whether any of the employees under your supervision have criminal records.

MR. FOGARTY: Objection.

A I would assume that they do not.

Q I am not asking you what you assume. I am asking you what you know.

MR. FOGARTY: Objection.

A I think I'm going to have to answer that in this manner:

I feel that the civil service procedure certainly relates to clearance for prior record of any type.

Q Do you know that for a fact or is that what you assume?

A I think that I would have to predicate that on my own personal experience because I've undergone civil service clearance.

As I recall, I've been fingerprinted. I filled out applications that related -- I think there were questions on there that related to medical history which if -- for example, if I answered incorrectly or falsely would be determined in the course of a Civil Service Department Investigation.

Q Now let me ask you my question and that is, Mr. Cannizzaro, whether you know whether any of the employees in the Bureau of Controlled Substances Licensing & Evaluation have criminal records.

MR. FOGARTY: Objection.

A I am going to say this. That I do not think they have it because of the fact that they go

through civil service screening. I've gone through it. And those are the areas that I was checked out. I was asked questions with regard to those areas.

Q Let me ask you again.

Do you know, Mr. Cannizzaro, whether or not any of the employees in the Bureau of Controlled Substances Licensing & Evaluation have criminal records?

MR. FOGARTY: Objection.

Q Can you tell me that none of them have criminal records, Mr. Cannizzaro?

MR. FOGARTY: Objection.

Q If so, please say so.

MR. FOGARTY: Same question.

MR. JAFFE: The question can be answered yes or no, though.

MR. FOGARTY: I didn't ask you for anything. I am making an objection on the record.

MR. JAFFE: I am responding to your objection. The question can be answered yes or no.

MR. FOGARTY: You are not to respond to my objection. You are not the judge.

MR. JAFFE: I understand that.

But I can respond. I am counsel.

MR. LESCH: Would you like the question read back, Mr. Cannizzaro?

THE WITNESS: I think I understand it, Mr. Lesch.

MR. LESCH: May I have an answer to it then?

A Yes, my answer is going to be that I don't believe that any of them have any criminal record because of the fact that they've undergone the same civil service security screening that I have.

MR. LESCH: Off the record.

(Discussion off the record.)

BY MR. LESCH:

Q Do you know, Mr. Cannizzaro, whether any of the employees of the Bureau of Controlled Substances Licensing & Evaluation have criminal records?

We've been sitting here and waiting for an answer now for about three minutes. Are you thinking about the question or are you just refusing to answer?

A I'm thinking about it, Mr. Lesch.

MR. FOGARTY: Let us have a five minute recess.

(Short recess.)

MR. LESCH: Will you read the question.

(Read question.)

A No, I don't definitely know that.

Q Mr. Cannizzaro, isn't it a fact that most of the employees that are listed on Exhibits A, B and D have started to work for the bureau which you supervise within the year preceding March, 1974?

A I think that statement is substantially true

Q Has there been a further turnover since March, 1974?

A Yes, sir.

Q So that many of the persons who are listed on Exhibits A, B and D are no longer employed by the Bureau of Controlled Substances Licensing & Evaluation, is that correct?

A Some of those are no longer employed by our bureau.

Q Have you obtained similar signed statements from the persons who have taken the place of the persons who are listed in the attachments to Exhibits A, B and D?

A Yes, sir, I have.

Q Mr. Cannizzaro, what is the turnover in your bureau every year?

A I haven't kept any records on the rate of turnover, but we've had some people leave and some other people take their place.

Q How many employees are there under your supervision?

A A total of 17.

Q Within the past year, how many of those 17 have been hired approximately?

A We may have five or six, possibly seven new ones.

Q What procedures do you follow to review the various security procedures with new employees?

A The -- we have a period -- an indoctrination procedure that is conducted by my principal clerk. And this matter of confidentiality is discussed even before the indoctrination when the people are first interviewed for positions.

But at the time that they definitely are coming with our bureau, then she will proceed to review the confidentiality memorandum with that individual and have them sign the sheet indicating that they have read it, are familiar with it, and are to abide by it.

And then she will then familiarize them with the layout of our area and the security procedures

that we have in existence, particularly with regard to the security area and the security vault.

Q Is there a test given to these employees to see whether they really understood what the confidential provisions are?

A We do not give any tests.

Q Is there any way then that you can determine that they've done any more than sign the memorandum?

A Just by observing them during the course of their daily activities.

Q Are the procedures in writing pursuant to which confidential provisions are reviewed with employees of your bureau?

A They read the confidential statement, and the memos that go with it, and they will also be reviewing the various logs that are kept and this new security of information from unauthorized disclosure. That will be circulated throughout our office for all of the staff to review and to sign a statement indicating that they have reviewed it, are familiar with it, and will abide by it.

Q Some of the employees who sign the attachment to Exhibit B are still in the employ of the Bureau of Controlled Substances Licensing & Evaluation, are they

not?

A Yes, sir.

Q Have they ever been requested to reread Exhibit B?

A Yes, I think there is an update on Item 83, and we recirculated a new memo with the new Item 83 attached, and they again signed the sheet to indicate that they had read it, are familiar with it, and would comply with it.

I think there were some minor revisions. I'm not totally aware of it right now.

Q Do you know that they actually read it?

A Do I personally know this?

Q Yes, sir..

A No. This procedure is conducted by -- under the supervision of my principal clerk.

Q You mentioned that in the coding area there are two temporary clerks in addition to seven civil service clerks, do you remember that?

A That's right, sir.

Q What check is made of the temporary clerks?

A I do not know. They are furnished to us through the personnel office of our department.

Q Is any credit check made of any of the

employees in your bureau?

A I do not know.

Q Is there any yearly routine for subsequent checks after the clerks are initially employed?

A No, there is no such routine.

Q What check is made of the key punch operators?

A That I don't know.

Q Are the temporary clerks civil service employees?

A The temporary clerks -- no, they are not civil service employees.

Q What is the volume of prescriptions processed per month?

A Approximately 125,000.

Q Do you know what the cost to the Department of Health is of the personnel that process the triplicate prescriptions both under your supervision and under the supervision of OEDP?

A There are some figures on that, but I don't -- I don't have those.

Q Would it be in excess of $1 million per year?

A Definitely not.

Q You are including in that answer the

computer time?

A Yes, yes.

I'm trying to recall. There are some figures being developed -- being developed by Dr. Baker. I don't think I have them as yet, final figures. But there is -- I think all the factors that are involved in the handling of the prescriptions are being taken into consideration to arrive at a total cost figure.

Q Approximately how many prescription blanks are there now in your posession? I am talking about filled prescription blanks that have been sent in by doctors or pharmacies under Article 33.

A Our rate of receipt is approximately 125,000 a month.

I cannot give you a good solid estimate for the simple reason that there is a period of time from April 1st through September of 1973 when prescriptions were being received and because of the -- of a court injunction they were not processed. So we don't have -- and we've not done anything with those prescriptions and we don't know what the actual volume count of those would be.

So I really couldn't give you a firm estimate other than to indicate to you that we are now

on a monthly basis processing, receiving and processing about 125,000 prescriptions a month.

Q Is it your intention to store all of those prescription blanks in the same vault that is currently being used to hold them?

A The prescription blanks?

Q The filled prescription blanks.

A The filled prescriptions, the cashed prescriptions?

Q Yes.

A We will store them in the present storage facility until such time as we move to our South Mall location, the Empire State Plaza, which is currently projected for March of 1975, and is dependent upon the construction of an adequate vault in the platform area of that building.

Q About how full is your vault now of these prescription blanks, can you tell me? Is it a fifth full, half full or is it almost all full of filled prescriptions?

MR. FOGARTY: Objection. That's irrelevant. There is a statutory obligation to store them.

MR. LESCH: You may answer,

Mr. Cannizzaro.

A In our present vault, I think probably maybe one-eighth the area is occupied by the cashed prescriptions and that's a real rough estimate.

Q How is access to the building controlled during normal working hours?

A That is public access.

Q Anyone can walk in?

A Into the building certainly.

Q How is access controlled during non-normal working hours? By that I mean after five or before nine in the morning.

A I think the doors to the building are locked somewhere between 4:45 and 5:00 p.m. each night.

Q Who has keys to the building?

A I don't know who has keys to the building. I know I do. I think Dr. Baker has a key. I don't know who else has a key to the building.

Q What is the method for controlling the number of keys to the building that are issued?

A I do not know that.

Q What happens when a key is lost?

A I don't know.

Q Mr. Cannizzaro, do you recognize that

there is a greater danger of unauthorized disclosure because the information on the triplicate prescriptions has been computerized?

MR. FOGARTY: Objection.

A No, I don't recognize that.

Q In your view then there is no greater danger now of unauthorized disclosure now that the state has it than it was before when the triplicate prescriptions were maintained in the pharmacy?

A No, I don't see any greater opportunity for disclosure under the present system.

Q As far as you are concerned, these provisions to maintain confidentiality are all unnecessary, is that right?

A I think they are definitely necessary.

Q Why are they necessary?

A To preserve the confidentiality of the document that's received by us centrally.

Q If there is no danger that the confidentiality is going to be violated, why is it necessary to take precautions to maintain the confidentiality?

MR. FOGARTY: Objection.

A Section 33.71 of Public Health Law requires us to maintain confidentiality with respect to any data

on these documents. So we follow the mandate of the statute.

Q But you don't recognize that aside from the mandate of the statute this information is of a confidential nature?

A I don't really understand your question.

Q Suppose there were no statute which required you to maintain the confidentiality, would you believe it incumbent upon you to see to it that there were confidentiality maintained for these documents?

MR. FOGARTY: Objection.

The question assumes a set of facts not in evidence, having nothing to do with the case.

MR. LESCH: You may answer.

A Well, I'm having difficulty comprehending your question. Just what is it that you do want to know?

Q You don't understand my question?

A No, I don't, frankly.

MR. FOGARTY: He is asking you if apples were oranges would you like them.

Q What I am asking you, Mr. Cannizzaro -- I think it is a revealing fact that you don't understand the question -- but what I am trying to get you to understand or get your answer to is do you recognize that

information on a prescription blank that sets forth the particular type of drug that a patient is receiving from his doctor is information which should be maintained confidentially regardless of whether there were a statute?

A This confidentiality requirement has existed before the triplicate prescription law. That -- I mean is that what you are saying? That was in existence prior to the current Article 33 which went into effect April 1, 1973.

This has always been true, maintenance of confidentiality.

Q Do you understand the reason for the statute?

A I probably don't understand all of the reasons for the statute.

Q Do you understand any reason why the statute should have been passed which required that these records be maintained as confidential?

A I'm saying to you that this confidentiality requirement existed prior to this current statute.

Q Regardless of when it was enacted --

A That's what I am trying to tell you. Maintenance of confidentiality on these prescriptions, not only the triplicate prescriptions, but prescriptions for other than Schedule II substances exists now and

existed prior to the current law for prescriptions that -- Schedule II substances that now require the triplicate prescription. This has always been the fact.

Q Let me try it once more.

Do you understand why these statutes have been passed, what the reason is why a legislature has passed a statute requiring that triplicate prescriptions or prescriptions containing information about the drugs that patients use should be maintained as confidential information?

MR. FOGARTY: Objection.

A Confidentiality was required prior to the triplicate prescription law and is still required is what I'm saying.

Q Mr. Cannizzaro, how many names from the printout of which Exhibit I is an example have you forwarded to the Bureau of Narcotic Controls since that printout was first issued in April, 1974?

MR. FOGARTY: Objection.

The question has been asked and answered before.

A I think we furnished you with copies of my quad weekly reports, and that type of information is included in there. I made numerous referrals, but I can't give you the -- a solid figure because I make

other types of referrals over to that do not necessarily relate to this particular printout. For example, forged prescriptions that may not be on that particular printout, excess purchase of prescriptions, and a few other items that are referred over for investigative follow-up, not necessarily from that one printout.

MR. LESCH: I have no further questions.

MR. JAFFE: I just have one or two here.

EXAMINATION BY MR. JAFFE:

Q Referring you to Defendant's Exhibit B, you stated under cross that you had 17 employees working for you, is that right?

A That's correct, sir.

Q And that does not include key punch operators, is that correct? They are not part of this group?

A They don't belong to the Bureau of Controlled Substance Licensing. That's an entirely --

Q Separate.

A -- separate unit.

MR. LESCH: May I ask one question just to clarify something?

BY MR. LESCH:

Q Dr. Baker called your unit Bureau of Controlled Substances Licensing & Evaluation.

A That's perfectly all right.

Q Is that the correct title or is it Bureau of Controlled Substances Licensing?

A Licensing & Evaluation would be adequate, but we -- a working title is Bureau of Controlled Substances Licensing.

MR. DONOVAN: Do you have people who have gradually dropped that word "evaluation"?

THE WITNESS: Right.

MR. DONOVAN: I think they created the word "evaluation" --

MR. GREENWALD: Is this off the record?

MR. LESCH: Let it be on the record.

MR. DONOVAN: I think it was created initially as we cleared up at the pretrial that the correct name was Bureau of Controlled Substances Licensing & Evaluation, but whether it was done officially or un-

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officially, it has gradually evolved to this Bureau of Controlled Substances Licensing.

BY MR. JAFFE:

Q In this connection, I call your attention to B, and in B you will see that there is a list of at minimum 24 employees, some permanent, other temporary.

A I think you'd have to delete those people that have been lined out. In other words, this was a continuing document showing additions and deletions of personnel.

Q So these were not all signed in March of 1974? There are several that are indicated that are not, but most are indicated were signed in March?

A We would ultimately have at any given time 17 people unless -- or less -- 17 or less, but not more.

Q How many of those would normally be temporary employees?

A Right now the normal is two.

Q It is indicated from the third page of that exhibit, for example, that there were six temporary employees on March 20, 1974. Is that correct?

A That would have been true on March 20, 1974, but today there are only two.

Q In March, 1974, who were these temporary

employees, that is to say, what was their background?

A I don't know that.

Q In what sense were they temporary?

A They were temporary service employees hired for our bureau through the personnel office of the Health Department.

Q Intended to work for a short period of time?

A There was no definite tenure indicated.

Q Do you know if the personnel office gave these temporary employees any background check whatsoever?

A No, I don't know.

Q And you don't know whether, for example, any of these people were checked for prior drug or criminal involvement?

A No, I don't know.

Q I take it these people left after a short tenure in your office?

A The tenure was a variable item. Some would be short and some would be long, some would be in-between.

Q Of the approximately 11 listed there, only two remain and it has been less than a year, is that correct? Referring to Page 3 of Item B.

A Right, two remain.

Q Are two of the names of the temporary employees still employees in your office?

A There may be possibly one of those still with us. We have an updated list.

Q But it's fair to say you know nothing about the background of these people?

A I have made no personal check. These people as I indicated to you were hired through our Personnel Department.

Q But it is perfectly possible that one of these people or more could have been employed on request of any politician, for example?

MR. FOGARTY: Objection.

Q As far as you know?

A I know nothing of the kind.

Q But you do not know that not to be true?

MR. FOGARTY: Objection.

A I don't know anything in that area. These people were hired through our Personnel Office. I make no personnel security checks myself.

Q And you know of none on these people?

A I know -- they are hired through the Personnel Department.

Q You have ability under the system to

monitor doctor use of Schedule II drugs, is that correct?

A Y , sir.

Q Do you do any evaluation of doctor use from the sheets you printout?

A We do some from the printouts, from some of the printouts.

Q Do you, for example, know what percentage of doctors with BNDD numbers prescribe Schedule II drugs?

A We could give you a figure on that. We'd have to calculate to determine that.

We could do that. We will ultimately.

Q But you have not done that to date?

A No, I haven't developed a definite figure. It wouldn't be too difficult.

Q You have no way of estimating that at this point?

A Oh, I can give you a rough estimate of approximately -- oh, let me see -- 70,000 -- 65, 70,000 practitioners -- and these are the various practitioners in the State of New York that hold a BNDD number with the Drug Enforcement Administration, and of those I'd say approximately 35,000 in any given month are using triplicate prescription forms.

That will vary from month to month.

Q If one looked at a period of a year, would there be a significant increase? Would there be any different number than one would get just looking at the month?

A I haven't done that, but I assume that with this first year's experience there would be a variation. In later years, it may stabilize.

Q You are also in a position to evaluate what percentage of those doctors, for example, would use 80 percent of Schedule II drugs used in the State?

A We will have the capability of doing that. We have it now.

We are making a study right now that relates to dispensing practitioners. We're evaluating those, and we will get data from the computer that will indicate to us who the primary dispensers are and the volumes that are represented by their activities.

In other words, number of prescriptions and number of patients.

Q And you will be able to pick out doctors who prescribe greatly in excess of what other doctors prescribe, is that correct?

A We'll get a spectrum. We'll setup a scale and they'll fall in the various gradations that are

determined.

Q For this it's true you do not need patient names, is that correct?

A We will definitely need patient names in the computers to give us that type of information because we're going to be determining, for example, how many different patients a doctor has. And the only way that that can be extracted is if the patient identity is in the computer so that it can make that determination.

Otherwise, without that information in the computer, it would not be able to differentiate one patient from another.

Q Isn't it a fact that without the patient's name you could pick out the amount each doctor is prescribing and the number of prescriptions that each doctor was given out?

A Numbers, yes, we can pick out numbers.

Q Isn't it true that if one doctor, for example, or many doctors were giving out much more than the other doctors, that you could most easily go to those doctors and find out from them the number of patients that each had?

A Well, you could do that, but we have the capability of differentiating, for example, between a

doctor that prescribes 100 -- utilizes 100 prescriptions and another one that also utilizes 100 prescriptions and the printout will readily tell us that the first doctor utilizes 100 prescriptions each for a different patient whereas the second patient who utilized 100 prescriptions it was all for the same patient.

Q That's readily available also by asking the doctor, isn't that correct?

A What basis would I have for asking the doctor? What am I going to ask him?

Q If you saw a doctor was using a great number of Schedule II drugs, you could ask that doctor how many patients he was prescribing for, could you not?

A Yes, we could ask that question.

Q But is it fair to say at the present time that you have no idea what percentage of doctors are prescribing what percentage of drugs, other than 100 percent of doctors prescribing 100 percent of drugs?

Let me put it differently.

You don't know if 20 percent of the doctors are prescribing it on percent of the drugs or if it is more evenly distributed than that, do you?

A We have a printout that's in evidence here that gives a breakdown of the total prescription

history that's processed in a given month that indicates that type of breakdown.

Q I understand that. My question --

A What you are asking about, in other words, the total number of prescriptions that had been processed and the total number of practitioners in a given -- in each of the given categories that has issued those prescriptions and the average number of prescriptions per practitioner type in that group, and I further indicated to you that we are going after data from that segment of the printout that relates to those practitioners that we've identified as dispensing practitioners to further refine that down to identify those that are the high volume dispensers for a low volume of patients.

Q My question was you have not done that evaluation at this point.

A We are doing it now. We are doing other evaluations, too.

Q So you could not tell us at this point where, if there are any, the major abuses are found in the prescribing of dangerous drugs or -- excuse me -- Schedule II drugs?

A I don't know whether these are going to be abuses. It will show major utilization. I think

before you can come to the conclusion that it is an abuse, I think the data has to be analyzed and then investigated.

Q My point is that at this point you have not done that and you don't know the answer to the question of where abuses may lie in the system?

A I don't have any definite answers to give to that question, other than to indicate to you that we are making studies of the -- at this time of the high volume dispensing practitioners.

Q You testified both on direct and on cross to two major changes in the printout system taking place since April of 1974, is that correct?

MR. FOGARTY: Objection to the use of the term "major".

A I think you better be more specific than that. Which changes are you referring to?

Q You testified that you now are printing out Exhibit F which may include as many as 100 sheets a month on which the names of patients appear, is that correct?

A I described the change in the format of that printout.

Q That is a change since April --

A Indicating that the substantive change was

the inclusion of the patient identity as it appears in the computer, together with a spatial separation between the various patients and a reorganization of the headings to provide a more utilizable format.

Q Is it fair to say that prior to the creation of Exhibit F there was no general printout of patient names, isn't that correct?

A I think I've indicated -- this was dated August. And I think in the questioning by Mr. Losch I was asked as to when this was started and my response was that it was probably sometime after April of 1974.

So that there would have been a printout prior to August, I'm certain, of 1974.

Q Since April then upon the date of which Exhibit F was created, this was the first time that patient names were printed out generally?

A I would say that that's true to the best of my knowledge.

MR. FOGARTY: Let the record indicate that Exhibit F has to do with August, not April. It's merely an update of Plaintiffs' Exhibit 18, I believe. The printout has been in existence from the beginning.

Q Did the printout which Mr. Fogarty has

referred to, Plaintiffs' Exhibit 18, include the names of patients on it?

A Can I see 18? I think I better make sure.

MR. FOGARTY: I think it is Exhibit 18.

THE WITNESS: Exhibit 18, this is one of the prototype printouts.

Q Did it have the patient names on it?

A No, it did not.

Q So the inclusion of patient names on that were the first time the patient names were printed out on the computerized printouts?

A Pardon me?

Q The inclusions of names on F was the first time going back to perhaps April that patients were printed out?

A Whenever this format was evolved -- and I think that was sometime subsequent to April -- I may be wrong on that -- just judging by my recollection -- that would be the first time that this printout indicated patient names.

Q Or that any printout indicated patient names?

A To my knowledge, this is the only one.

Q Isn't it also true that you now have a new

capability, that of requesting the computer to give back the name of a particular patient and that prior to April of this year that capability did not exist?

A Yes, I've testified to that.

Q Who made these determinations to change the accessibility of names and the printing out of names?

A Which changes are you talking about now? These were separate items. You are talking about two different printouts, types of printouts.

Q Start with the printing out of names and go onto the accessibility of names.

A Are you talking about Exhibit F?

Q Exhibit F.

A That determination was made sometime -- I am going to guess again -- sometime after February of this year.

Q By whom?

A 1974.

My instructions on it came from my boss, the Associate Commissioner of Community Health Services, Dr. Arthur Baker.

Q What about the decision to have the names on the computer accessible upon request? Who made the decision to program the computer in that way?

A Approval -- approval for me to do that came from Dr. Baker.

Q But you requested it?

A This thing was under review. I didn't have to make a request.

Q Do you know of any regulation which restricts you or your department from printing out the name of every patient on every prescription that comes into your office?

A I think that particular item would be covered under our security information from unauthorized disclosure, plus the -- plus Item 83 of the manual, general administrative manual, plus Section 33.71 of the Public Health Law.

Q You are referring at first to Exhibit E, is that correct?

A If you will show me Exhibit E.

Q Here is E. I show you Exhibit E. That is the unauthorized disclosure, is that correct?

A Yes.

Q Unauthorized disclosure memorandum to which you referred?

A Right.

Q Is there anything in that memorandum which

indicates that you could not printout the name of every patient on every prescription that comes into your department?

A We have the capability of printing out every name.

Q Is there any --

A Getting a printout from the computer?

We could ask the computer to do that.

Q And there is no regulation which prevents you from doing that, to your knowledge?

A I don't believe that -- let me put it to you this way:

That would not be generated without authorization from Dr. Baker.

Q But there is nothing which restricts Dr. Baker from doing that, to your knowledge?

A I don't know.

Q In other words, if you feel it's useful that every single name of every single patient be printed out, you would not know of any regulation which would prevent you from asking Dr. Baker to authorize such a printout?

A I could ask.

Q But at this point you know of no such

regulation?

A That would prevent me from asking him?

I could ask any day. I doubt that I'd ever get approval.

MR. JAFFE: That is all.

BY MR. FOGARTY:

Q Mr. Cannizzaro, does your department operate on a budget?

A Yes, sir, it does.

Q What would it cost, a rough estimate, to printout every name on every prescription?

A I think if we ever tried that I think they'd probably close us up.

To put it another way. It's not practical, it's not feasible. It's not reasonable.

Q Let's assume, Mr. Cannizzaro, that you got the printout with every name on every prescription. What would you do with it?

A First I'd have a problem finding storage space with it, and I don't see how it would be practical to make any utilization of it. It's too voluminous. It would be too voluminous.

Q What would you have to do in order to get pertinent information out of such a printout?

A Actually it would have to go back into the computer, I mean, to get data out of it.

Q Let's assume that you have gotten out of the computer what was just suggested, a complete printout of every name on every prescription. In order to make any effective use of that, what would you have to do?

A It would be just as impossible as the investigators going from pharmacy to pharmacy to scan prescriptions because you'd have to have a battery of personnel just to review the listings of the patients on the printout.

Q In other words, it would have to be scanned item by item?

A Item by item manually.

Q Then somebody else would have to be collating the information?

A It would be an impossible task.

Q When this printout with the names comes out of the computer, and it is delivered to you, where does it go.

A It comes immediately to me from my principal clerk after it's logged in, and I lock it in my special computer cabinet, computer printout cabinet.

I put all of the monthly printouts in there.

Q Does anybody else get a copy of it?

A No, sir.

Q Do you send it to anyone?

A No, sir.

The -- let me correct that.

The only copies that are made are those that are statistical in nature and I furnish that copy to Dr. Baker as the prescriptions --

Q But those don't contain patient names?

A No, there is no patient identity.

Q In other words, the patient identity printout comes to you and it stops at you?

A Right. And it's not utilized unless I authorize it's utilization.

Q Mr. Cannizzaro, the only printout containing patient names on a regular basis is Defendant's Exhibit F, is that correct?

A That's correct, sir.

Q Any other printout with a name, a patient name, would be made as a result of a request?

A That is correct, sir, a specific request.

Q That specific request, what would have to happen to it before it got to the OEDP?

A It would initially have to be submitted

to our office from the Bureau of Narcotic Enforcement, where it would be checked to see that it was properly executed.

After initialing by my principal clerk and then myself, it would then be sent along with a data form that we send to Data Processing, both of them in triplicate to Dr. Baker for his review and approval on both forms.

It would then come back to us, assuming that it is approved -- let us stick with that -- and at that point -- and he would retain a copy of each form for his records.

The Data Processing form would not have any identity on it other than, for example, a BNDD number. There would be no other identity on it.

After he has approved it, we would then generate -- complete the Data Processing request form and forward that containing Dr. Baker's approval and my approval to the director of the Office of Electronic Data Processing for generation of the requested printout.

And then when the printout was ready, when we were notified, then it would be picked up, at which time a countersignature would be executed on the form, indicating the number of copies that were requested

and received, and then upon receipt in our office it would be logged in. There is a special data request number file setup for each request.

And after we had received -- when we have received the requested printout, we would then notify the Bureau of Narcotic Enforcement that that printout, requested printout was ready. They would come down, complete the execution of the receipt, double signature forms, and depart with their copies in a sealed envelope together with a copy of the initial request, which would be keyed to the identifying number of the printout on the envelope.

And that's it in substance. It's more fully described, more completely described from our security information from unauthorized disclosure procedure. It's quite complex.

Q In describing the procedure, you also mentioned it comes down. Why did you use that expression?

A I think that was in reference to the initial request from the Bureau of Narcotic Enforcement. I said down because they are located on the first floor which is ground level at the front and we're located on the second floor of the same building, which is ground level in the area that we're located.

Q Are you actually on the second floor or are you in the basement?

A It's in the basement, but we refer to it as the ground floor.

Q In other words, in order to reach the area where you are located, someone has to come in the front door and go downstairs?

A Right. You come in the front door and go to the end of the front corridor, take the stairway down and then you come into our area, walk down that corridor. On the left will be the administrative area where I'm located, and on the right in a separate and entirely separate area will be the security area that is -- which contains within it the prescription processing area. To get into the security area, you have to go through a locked gate which has to be unlatched and which is controlled by the supervising prescription clerk.

And then beyond that, we have the separate area that is separated by the heavy gauge screened fencing from floor to ceiling.

And then alongside that, across the corridor is located our security vault, which is entirely separate. And in order to gain access to the vault, you must have clearance from me. And to get into my office,

you must go through a locked gate, which is controlled by my secretary.

Q Mr. Cannizzaro, referring to Defendant's Exhibits A, B and D, after your name, Mr. Cannizzaro, Joseph L. Cannizzaro, Director, what does the exhibit contain?

A My initials.

Q In other words, you signed it, right?

A That's correct, sir.

Q What are the first three words of each memo? We will start with A and D.

A A and B is directed --

Q What are the first three words? That's all I ask.

A I'm trying to get them together. "We should all," contents of the memo.

Q Are you part of we?

A Yes, I am.

MR. FOGARTY: That's all.

MR. LESCH: I have a few more questions.

BY MR. LESCH:

Q Mr. Cannizzaro, do you have a copy of Plaintiffs' Exhibit 14 before you?

A Yes, sir.

This is the one you have just given me?

Q Yes. That printout contains a summary of all prescriptions processed in the month of -- dispensed and processed in the month of February, 1974.

A That's the top sheet, I think, of that printout.

Q This shows you an average quantity of Schedule II substances dispensed for each doctor in the State of New York, does it not?

A These are broken down by practitioner groups. First we're given total, and then this would be -- where it says MD, that would be physicians, DO, would be osteopaths, DDS, would be dentists, DPM's, would be veterinarians, and Dr. POD, would be podiatrist.

Q So that by reference to Exhibit 14, you are able to determine the average quantity of a particular Schedule II substance that is dispensed by all the doctors in the State of New York, is that correct?

A Primarily processed during that particular month.

Q During a particular month?

A Right, processed, prescription processed.

Q For example, for a drug which bears the

NDC number 318, you can ascertain the average quantity of that drug that is prescribed in that month by all doctors, is that right?

A Right, there would be a breakdown for total practitioners and then by individual practitioner groups.

Q So you could not only tell the average prescribed by every practitioner, but you could ascertain the average prescribed by every MD, every doctor of osteopathy, every dentist, every doctor of veterinarian medicine and every -- what is Dr. POD stand for?

A Podiatrist.

Q Podiatrist?

A This again is by practitioner groups.

Q By practitioner groups?

A By practitioner groups not by individual practitioner.

Q So that if you have a doctor whom you suspect is dispensing or prescribing too many drugs of any particular type, you could compare the total amount that that doctor prescribes with the average for the practitioner group to which he belongs, is that right?

A That can be done.

Q Then after you have done that, investiga-

tion could be made to determine whether there is a good reason for that doctor to prescribe an amount exceeding the average, is that correct?

A That can be done, certainly.

Q Is there a printout which shows the numbers of the prescription blanks that have been mailed to all doctors in the State of New York?

A We have a printout that is furnished to us or has been furnished to us wherein we keep track of our prescription supplies showing the various serial numbers and to whom they have been sold. That would be in numerical sequence as the prescriptions are sold.

Q How by reference to these printouts do you ascertain whether a stolen blank has been cashed?

A That's done in this fashion.

We have setup in the computer a listing of all reports of lost, stolen, etc., prescriptions which we constantly maintain.

When a prescription is processed and placed in the computer, it is automatically run against that listing in the computer.

If it appears that that particular serial number on that prescription has -- is on the lost-stolen list, we will get that particular printout that indicates

that a lost-stolen prescription has been previously reported lost or stolen has been cashed, and gives us the identifying data.

Q So that the number on the prescription that is received by your bureau is run against the number that is already contained on the list within the computer as a lost or stolen prescription and if it is the same number, you will know that one may be a lost or stolen prescription, is that right?

A The computer definitely says that that is on the list that has been reported lost or stolen and it has been filled.

Q The way that is done is that the number of the prescription blank that you receive is compared with the number that is actually on the computer tape, is that right?

A Right. To my knowledge, that's the way it's done.

Q So that the patient name is not needed in order to ascertain that information, correct?

A No, it's not needed.

Q The information contained on Plaintiffs' Exhibit 15 is of value to the Department of Health, is it not?

A Yes, sir, it is.

Q What is that information used for?

A We have been keeping track of the average rate of utilization of prescriptions by the various practitioners, both in the area of prescribing and dispensing, also determining the averages that are being filled by pharmacies specifically.

Q Is one of the uses so that you could compare those averages with any particularly suspicious doctor or pharmacy?

A This is not used on an individual focus basis. In other words, to focus on any particular physician, doctor, patient, you know, or pharmacy.

This is -- gives you a statistical summarization of the prescriptions that have been processed during the month and indicates to you which of the particular groups are making the greatest utilization of the prescriptions.

Q I understand that. But isn't it the case that one use for Exhibit 15 is to compare the average number of prescriptions per practitioner, for example, per MD, with any particular doctor in whom you are interested in order to ascertain whether that doctor falls above or below the average, and if he falls above

the average so that could make an appropriate investigation?

A This may be a utilization that we will be making. We are not currently doing that.

Q What are you currently using Plaintiffs' Exhibit 15 for?

A To determine the averages and to see if there are any changes in the averages from month to month.

Q Why are you interested in any changes in the averages from month to month?

A Well, we'd like to know if there is an increase or decrease in prescription utilization by the total averages or by practitioner group averages which might be indicative of a need for investigative follow-up for one thing or look into a given group.

Q Of course, for such an investigative follow-up, you would not need the patient names, isn't that right?

A No, I wouldn't say that. That would be a variable. We're speaking very generally now. That would not be true, I'm sure.

Q Exhibit 16 is a report of duplicate prescriptions processed in the month of February. What is that used for?

A That is used as a check on the possibility of a counterfeiting of the actual triplicate prescription form.

What this printout indicates to us is that there has been more than one prescription entered into the computer with the same serial number.

So we follow this up by means of going to the indicated batches and to determine whether it is a counterfeit prescription or whether it is some sort of processing error, either in our unit or the Key Punch Unit, or whether there is some other explanation for the duplicate entry with the same serial number in the system.

Q You would obtain Plaintiffs' Exhibit 16 even if the prescriptions that you received did not contain the patient's name, would you not?

A That's correct, sir. Designed to give only the prescription serial number and the batch number of the prescriptions.

Q Similarly you would be able to obtain Exhibit 15 without the names of the patients listed on the prescription, isn't that correct?

A That's correct. The patient names are not indicated on that. It's strictly statistical.

Q What is Exhibit 17 used for?

A I indicated to you that we're not making current utilization of that. We're not currently receiving that.

Q What is Exhibit 19 used for?

A This is in connection with our processing of application for triplicate prescription blanks wherein the patient names would not be involved.

Q Do Exhibits 19, 20 and 21 have any use other than in the processing of triplicate prescription information on the computer?

A No, these again relate the same as the prior exhibit to the processing of applications from practitioners for supplies of triplicate prescription blanks and would not involve patient names.

MR. LESCH: I have no further questions.

MR. FOGARTY: No further questions.

(Time noted: 4:35 p.m.)

Joseph L. Cannizzaro

Subscribed and sworn to before me

this 13 day of February, 1975.

C E R T I F I C A T E

STATE OF NEW YORK)
: ss
COUNTY OF NEW YORK)

I, WILLIAM BLITZ, a Certified Shorthand Reporter and Notary Public within and for the State of New York, do hereby certify:

That JOSEPH L. CANNIZZARO, the witness whose deposition is hereinbefore set forth, was duly sworn by me and that such deposition is a true record of the testimony given by such witness.

I further certify that I am not related to any of the parties to this action by blood or marriage, and that I am in no way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 18 day of December, 1974.

William Blitz

WILLIAM BLITZ, CSR

I N D E X

WITNESSES

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EXHIBITS

DEFENDANT'S TRIAL		FOR IDENT.
A	Memorandum dated March 8, 1974 entitled "Confidentiality of Records" from Joseph L. Cannizzaro to all non-bureau employees,	20
B	Memorandum dated March 11, 1974 entitled "Confidentiality of Records" from Joseph L. Cannizzaro to all employees in the Bureau of Controlled Substances Licensing,	20
C	Document headed "General Administration Manual" dated 2/27/74, Item 83,	21
D	Memorandum dated March 18, 1974 entitled "Access to the Vault and Security Area" from Joseph L. Cannizzaro to all employees of the Bureau of Controlled Substances Licensing,	31

EXHIBITS (cont'd)

DEFENDANT'S TRIAL		FOR IDENT.
E	Document headed "Bureau of Controlled Substances Licensing, Security of Information from Unauthorized Disclosure,"	33
F	Update of Plaintiffs' Trial Exhibit 18,	44
G	Document headed "Cashed Rx's Previously Reported Lost Or Stolen,"	47
H	Document headed "Bureau of Controlled Substances Licensing, Triplicate Prescriptions Record Retention, Purging of Prescription Files."	63

PLAINTIFFS' TRIAL		
42	Document dated March 22, 1973 on the letterhead of The State Commissioner of Health, Albany, New York.	83

oOo

Notice of Motions to Amend the Pre-Trial Order.

[SAME TITLE]

Sirs:

Please take notice that upon the annexed affidavit of A. Seth Greenwald, duly sworn to the 11th day of April, 1975, the undersigned will move this Court on the 25th day of April, 1975 in Room 705, at 10 o'clock in the forenoon, United States Courthouse, Foley Square, New York, New York for an order amending the pre-trial order to reflect the annexed schedule of defendant's exhibits placed in evidence on trial depositions, to further amend the pre-trial order as to print-outs including patient identity, to grant defendant's judgment on the close of plaintiffs' *prima facie* case and exclude the testimony of Joseph Wasserman as not having any foundation in plaintiffs' *prima facie* case and for such other and further relief as may be just and proper.

Dated: New York, New York, April 11, 1975.

Yours, etc.,

Louis J. Lefkowitz
Attorney General of the
State of New York
Attorney for Defendant

By A. Seth Greenwald
Assistant Attorney General

Notice of Motions to Amend the Pre-Trial Order.

To: Shea, Gould, Climenko,
Kramer & Casey

Solomon Z. Ferziger, Esq.
Attorneys for Plaintiff Richard Roe,
et al.

Elizabeth B. DuBois
Legal Action Center
and
Norwick, Raggio & Jaffe
Attorneys for Plaintiffs-Intervenors
George Patient, et al.

Affidavit of A. Seth Greenwald, in Support of Motion.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

RICHARD ROE, an infant, by ROBERT ROE, his parent, et al.,

Plaintiffs,

and

GEORGE PATIENT, et al.,

Plaintiffs-Intervenors,

against

HOLLIS S. INGRAHAM, as Commissioner of Health of the State of New York,

Defendant.

STATE OF NEW YORK }
COUNTY OF NEW YORK } ss.:

A. SETH GREENWALD, being duly sworn, deposes and says:

I am an Assistant Attorney General in the office of Louis J. Lefkowitz, Attorney General of the State of New York, attorney for defendant herein and make this affidavit in support of the motions addressed to the Court.

I

The defendant is moving to amend the Pre-trial Order list of defendant's exhibits to reflect those introduced at the trial depositions. These consist of a Schedule annexed

Affidavit of A. Seth Greenwald.

Exhibits "A" through "N". These exhibits present a complete picture of defendant's use of triplicate prescriptions involving patient identity and security procedures designed to insure confidentiality of patient identity as required by law. Public Health Law (N.Y.) § 3371. It is submitted that the plaintiffs were not prejudiced by their use during trial depositions and the substance of these exhibits were all available to plaintiffs prior to trial. There is no "surprise" involved. They are an integral part of the testimony adduced by defendant and should be a part of the record of this case.

It should be emphasized that the introduction of these exhibits is in no way a concession that security or procedures of defendant is a proper issue. The plaintiffs utterly failed to show any breach of security as to triplicate prescriptions or even allege or testify that defendant has ever disclosed plaintiffs' identity from the processing or computerization of triplicate prescriptions in his custody pursuant to law.

II

During trial depositions some question came up as to receipt of computer print-outs including patient identity. (Testimony of Joseph Cannuzzaro). Defendant's Exhibit "F" is the only print-out *regularly* received with patient identity. However the pre-trial order should reflect that, on special request, print-outs on specific patients are produced. This, of course, is not a regular print-out.

III

As set forth in defendant's post-trial memorandum (Point I) the defendant should be granted judgment on the close of plaintiffs' *prima facie* case as they failed to

present an actual case of controversy or show standing to maintain the action. There was utterly no testimony defendant had ever disclosed any plaintiffs' identity, within or without the confines of the Public Health Law.

IV

Defendant is also moving to exclude the testimony of plaintiffs' security expert Joseph Wasserman, as his testimony had no foundation in plaintiff's *prima facie* case. As set forth in defendant's post-trial memorandum, Point II, pp. 27 *et seq.*, no plaintiff patient ever testified to lack of security as the basis of his "fears". Mr. Wasserman was testifying in a complete vacuum. His testimony should be excluded.

WHEREFORE, your deponent respectfully requests that the motions be granted.

(Sworn to by A. Seth Greenwald, April 11, 1975.)

Exhibit A, Defendant's Amended List of Trial Exhibits.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

INDEX NO.
73 Civ. 1303
(RLC—3 Judge Court)

RICHARD ROE, an infant, by ROBERT ROE, his parent, JOHN DOE, an infant, by MARY DOE, his parent, JAMES MOE, an infant, by MICHAEL MOE, his parent, JANE POE, MATTHEW T. BRODY, ISRAEL L. SCHMIERER and EMPIRE STATE PHYSICIANS GUILD, INC.,

Plaintiffs,

—and—

GEORGE PATIENT, MARTHA PATIENT, GERALD L. LUSTIG and THE AMERICAN FEDERATION OF PHYSICIANS AND DENTIST,

Additional Plaintiffs,

—against—

HOLLIS S. INGRAHAM, as Commissioner of Health of the State of New York,

Defendant.

A	Memorandum dated March 8, 1974 entitled "Confidentiality of Records" from Joseph L. Cannizzaro to all non-bureau employees,
B	Memorandum dated March 11, 1974 entitled "Confidentiality of Records" from Joseph L. Cannizzaro to all employees in the Bureau of Controlled Substances Licensing,

Exhibit A, Defendant's Amended List of Trial Exhibits.

C — Document headed "General Administration Manual" dated 2/27/74, Item 83,

D — Memorandum dated March 18, 1974 entitled "Access to the Vault and Security Area" from Joseph L. Cannizzaro to all employees of the Bureau of Controlled Substances Licensing,

E — Document entitled "Bureau of Controlled Substances Licensing Security of Information from Unauthorized Disclosure."

F — Print out entitled "Patients with Rx Total Dose in excess of 30 day supply processed in month of August."

G — Print out entitled "Cashed RXS previously reported lost or stolen."

H — Document entitled "Bureau of Controlled Substances Licensing Triplicate Prescriptions Record Retention Purging of Precription Files."

I — 4x6 salmon colored card with printing on it,

J — Document dated July 23, 1973 entitled "Confidentiality of Records."

K — Document dated July 27, 1973 entitled "Security Procedures For Operations Section of EDP."

L — Document dated July 31, 1973,

M — Document headed "Office Reference Manual, Item 2."

N — Document entitled "Confidentiality Of Information."

Order Substituting Defendant.

[SAME TITLE]

Upon the annexed affidavit of Michael Lesch, Esq., sworn to on August 18, 1975, it is

ORDERED, pursuant to Fed. R. Civ. P., Rule 25(d), that Robert P. Whalen, Commissioner of Health of the State of New York, be and he hereby is substituted as the defendant in the above entitled action in place and stead of his predecessor Hollis S. Ingraham; and it is further

ORDERED that the caption of the above action shall hereafter be as follows:

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

RICHARD ROE, an infant by ROBERT ROE, his parent; JOHN DOE, an infant by MARY DOE, his parent; JAMES MOE, an infant by MICHAEL MOE, his parent; JANE POE, MATTHEW T. BRODY, ISRAEL L. SCHMIERER, and EMPIRE STATE PHYSICIANS GUILD, INC.,

Plaintiffs,

against

ROBERT P. WHALEN, as Commissioner of the State of New York Health Department,

Defendant,

GEORGE PATIENT, MARTHA PATIENT, GERALD L. LUSTIG, and THE AMERICAN FEDERATION OF PHYSICIANS AND DENTISTS,

Intervenors.

Dated: New York, New York, October 3, 1975.

s/ ROBERT L. CARTER,
U.S.D.J.

Final Order and Judgment (Reproduced at Jurisdictional Statement p. 14a).

Notice of Appeal (Reproduced at Jurisdictional Statement p. 18a).

Opinion Denying Stay, Justice Marshall (Reproduced at Jurisdictional Statement p. 39a).

Supreme Court, U. S.
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IN THE

Supreme Court of the United States

OCTOBER TERM, 1975

No. 75-839

ROBERT P. WHALEN, as Commissioner of Health of the State of New York,

Appellant,

—against—

RICHARD ROE, an infant by ROBERT ROE, his parent; JOHN DOE, an infant by MARY DOE, his parent, JAMES MOE, an infant by MICHAEL MOE, his parent; JANE POE, MATTHEW T. BRODY, ISRAEL L. SCHMIERER and EMPIRE STATE PHYSICIANS GUILD, INC.,

Appellees,

—and—

GEORGE PATIENT, MARTHA PATIENT, GERALD L. LUSTIG and THE AMERICAN FEDERATION OF PHYSICIANS AND DENTISTS,

Intervenor-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

APPELLEES' MOTION TO AFFIRM

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IN THE

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ROBERT P. WHALEN, as Commissioner of Health of the State of New York,

Appellant,

—against—

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ON APPEAL FROM THE UNITED STATES DISTRICT COURT
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APPELLEES' MOTION TO AFFIRM

Statement

Appellees Richard Roe, John Doe, James Moe, Jane Poe, Matthew T. Brody, Israel L. Schmierer and Empire State Physicians Guild, Inc., pursuant to Rule 16 of the Revised Rules of the Supreme Court of the United States, move that the final order and judgment of the District Court be affirmed on the ground that the contentions attempting to support the constitutionality of the challenged statutory provisions are so unsubstantial as not to warrant further argument.

Question Presented

Whether the Court below correctly held that Sections 3331(6), 3332(2) and 3333(4) of the New York Public Health Law, to the extent that they require automatic routine and massive reporting to the State of the names, addresses and ages of all patients who receive treatments by Schedule II controlled substances, unconstitutionally interfere with plaintiffs' rights of privacy guaranteed under the Fourteenth Amendment.

Statement of the Case

This is a direct appeal from the final order and judgment entered on October 9, 1975 by a district court of three judges constituted pursuant to 28 U.S.C. §§2281 and 2284. The final order and judgment declared unconstitutional and enjoined enforcement of three specific provisions of the New York Public Health Law—§§3331(6), 3332(2) and 3333(4)—"insofar as they require disclosure to the State of New York of the identity of patients receiving prescriptions for Schedule II controlled substances" (14a-17a at pars. 1, 2).* In addition, the judgment directed the destruction of New York prescription forms previously filed pursuant to the statute, the expungement of patients' names from records made from the prescription forms and the filing of an affidavit describing the time, place and manner of such destruction and expungement (14a-17a at pars. 3, 4). At the request of the State, a stay of the paragraphs of the judgment relating to destruction of the

* Numbers in parentheses preceding the letter "a" refer to pages of the appendix following appellant's Jurisdictional Statement herein.

records was granted by the three-judge court pending disposition of appellant's appeal or other order of this Court (16a at par. 5). The State's applications for a broader stay were denied by the Court of Appeals on October 20, 1975 and by Justice Marshall on October 28, 1975 (39a-43a).

Roe, et al. v. *Ingraham** was commenced on March 29, 1973 in the United States District Court for the Southern District of New York. On that date, the Court (Hon. Robert L. Carter, U.S.D.J.), granted an order temporarily restraining defendant from filing or processing prescription forms revealing the identity of patients receiving Schedule II drugs and from requiring pharmacists or physicians to file such forms and affirmatively directing defendant to retain any such prescription forms received by the State in a sealed vault or other equally secure place.

Subsequently, by an order and opinion rendered orally on April 6, 1973, the Court dismissed the complaint for want of a substantial federal question, but granted a temporary restraining order and dissolved the temporary restraining order previously granted. To permit plaintiffs to seek a stay and to perfect their appeal to the United States Court of Appeals, however, the District Court extended until April 9, 1973 at 12 noon so much of the order as provided for retention by defendant of the prescription forms in a sealed vault. The opinion, as subsequently filed, is reported as *Roe* v. *Ingraham,* 357 F.Supp. 1217 (S.D.N.Y. 1973).

On April 9, 1973, the Court of Appeals (Hon. J. Joseph Smith, Paul R. Hays and William H. Timbers, Circuit

* By order made October 2, 1975, Robert P. Whalen, the present Commissioner of Health of the State of New York, was substituted as defendant in place of his predecessor, Hollis S. Ingraham.

Judges) continued in effect the temporary restraining order, as modified, pending an appeal.

On May 24, 1973, the Court of Appeals (Hon. Henry J. Friendly, Chief Judge, Paul R. Hays, Circuit Judge and William J. Jameson, District Judge sitting by designation) reversed the District Court's order and held that the complaints stated a substantial federal constitutional question, that plaintiffs were entitled to a continuation of the temporary restraining order, that a three-judge court should be convened, and that the three-judge court should determine whether to grant a preliminary injunction. *Roe* v. *Ingraham,* 480 F.2d 102 (2d Cir. 1973). On August 23, 1973, the three-judge court (Hon. Wilfred Feinberg, Circuit Judge, Hon. Robert L. Carter, District Judge and Hon. Inzer B. Wyatt, District Judge) dissolved the temporary restraining order, denied plaintiffs' motion for a preliminary injunction, and denied defendant's cross-motion for an order dismissing the complaints. *Roe* v. *Ingraham,* 364 F.Supp. 536 (S.D.N.Y. 1973).

After pretrial discovery, the *Roe* and *Patient* actions were formally consolidated. In addition, two pretrial orders on consent governing the conduct of the trial were made. The first, made on November 18, 1974, set forth a stipulation of facts, the issues to be tried and the exhibits, witnesses and contentions upon which the parties would rely. The second, made on November 21, 1974, provided that the trial testimony of plaintiffs' expert witnesses and defendant's witnesses would be submitted to the Court in deposition form, and that the remainder of the trial would take place before the three-judge court. The trial and depositions were concluded on December 6, 1974.

On August 13, 1975, the three-judge court filed its unanimous opinion holding that "so much of the New York Health Law as requires reporting to state authorities in Albany the names and addresses of patients who receive Schedule II drugs as medication prescribed by duly licensed physicians is an unconstitutional interference with plaintiffs' right of privacy guaranteed under the Fourteenth Amendment" (13a).

The Court noted that "[a]n individual's physical ills and disabilities, the medication he takes, the frequency of his medical consultation are among the most sensitive of personal and psychological sensibilities" (10a); recognized that "there is legitimate concern that information that one, one's children or an intimate is under treatment with such drugs not be broadcast to unauthorized sources" (10a); stated that "the state effort to control drug abuse and to prevent illegal trafficking in dangerous drugs fosters a legitimate state purpose" (11a); found that "admittedly the only purpose this information [names, addresses and ages of patients receiving Schedule II drugs] serves is to identify individual patients who without using an alias go from doctor to doctor to secure Schedule II drugs and those individuals who secure more than a 30-day supply in a single month" and that "[d]uring the 20-month life of the program only one such unresolved incident in this category has been unearthed" (11a); and held that "[t]he diminution of a constitutionally guaranteed freedom is too great a price to pay for such a small constitutional yield" (11a).

On October 28, 1975, Hon. Justice Thurgood Marshall, having heard oral argument, denied appellant's motion for a stay of the provisions of the final order and judgment below granting declaratory and injunctive relief (39a-43a).

Facts

Roe, et al. v. *Ingraham* was brought by four patients,* including three infants and one adult receiving medications set forth in Schedule II of §3306 of the New York Public Health Law (hereinafter "Schedule II drugs") (Tr. 5-6, 28, 61-2, 102-3; Compl., par. 4),** two named doctors who prescribe such drugs (Tr. 37-9, 75-6; Compl., par. 5), and The Empire State Physicians Guild, Inc., a New York Membership Corporation representing the interests of certain New York physicians (Tr. 76). *Patient, et al.* v. *Ingraham* was brought by a post-operative cancer patient and an individual suffering from migraine headaches, both of whom received Schedule II drugs as medication (Tr. 86-9, 31-4; Compl., par. 5), the doctor of one of these patients (Tr. 94-101; Compl., par. 6) and The American Federation of Physicians and Dentists (Compl., par. 7).

The gravamen of plaintiffs' claim was that certain provisions of Article 33 of the New York Public Health Law

* The State asserts that the patient plaintiffs are "anonymous" (Jurisdictional Statement, p. 7). This is incorrect. The identity of the patient plaintiffs was provided to defendant and the Court below and all plaintiffs testified in open court during the trial. To protect their privacy, however, the Court permitted such plaintiffs to prosecute the action under pseudonyms.

** Numbers or letters in parentheses preceded by "Tr." refer to pages of the transcript of the trial held on December 2, 1974; numbers preceded by the name of a witness (e.g., Wasserman 40) refer to pages of the deposition transcript of the trial testimony given on December 4, 5 and 6, 1974 pursuant to the November 21, 1974 Pretrial Order on Consent.

In addition, numbers preceded by "Ex." refer to trial exhibits and numbers preceded by "Stip., par." refer to paragraphs in the Stipulation of Facts included in the Pretrial Order on Consent made on November 18, 1974.

(hereinafter "Article 33" of "the Act") are unconstitutional insofar as they require physicians and pharmacists to file with the State of New York prescriptions revealing the identity of patients using Schedule II drugs. The challenged provisions require (a) that all Schedule II drugs be prescribed on prescription forms containing, *inter alia*, the name, address and age of the patient (§3332(2)) and (b) that copies of such prescription forms for Schedule II drugs, which in every case contain the identity of persons using the medication, must be sent to the Department of Health of the State of New York each and every time they are prescribed (§§3331(6) and 3333(4)).* Plaintiffs contended that the foregoing provisions violate the Fourteenth Amendment of the United States Constitution in that they unnecessarily invade the patient's right of privacy and the doctor's right to prescribe treatment for his patients solely on the basis of medical considerations.

The information acquired by the State is "coded" into a centralized computer and used in enforcement of Article 33. The Act contains no limitation on the sweeping requirement that copies of all prescriptions for Schedule II drugs (including thereon the names of the patients) must be filed.

* Contrary to the State's assertion (Jurisdictional Statement, p. 21), the Court below did not make the "strange" assumption "that the State had no interest in addicts." The Court held that "[t]here is no state claim that the names on the form will be of aid in preventing addicts from access to drugs by prescription" (11a, fn.). There never has been such a claim because the provisions challenged herein do not apply to addicts. Section 3331(1) specifically provides that the provisions of Title IV (which include the filing requirements) do not apply to the prescribing or dispensing of controlled substances to an "addict" or "habitual user", terms defined in §§3302(1) and 3302(17) respectively. Prescribing and dispensing of controlled substances to addicts are governed by Titles III and V of the Act.

There is no provision for any summons, either judicial or administrative, as the means whereby the Department of Health is required, in the usual case, to demand reports from doctors and pharmacists. The Department is required by the Act to demand and obtain such reports routinely, automatically, from all physicians and pharmacists in the State without any process whereby the physicians or pharmacists or patients may test in advance the reasonableness of the demand. Until entry of the final order and judgment below, approximately 125,000 prescriptions were received by the State and coded onto the computer each month by a staff of over 30 clerks and keypunch operators.

The legislative history of the Act* reveals that no consideration at all was given to the question whether there is any need for the filing and computerization of patients' names. Most of the legislative history is devoted to provisions of Article 220 of the Penal Law enacted together with Article 33 and to provisions of Article 33 not challenged hereby or relevant to this case. In the rare instances where the triplicate prescription provisions were discussed—principally on two pages of the 1972 Interim Report (Ex. 32, pp. 21-2) and the Hardt Memorandum (Ex. 33)—the discussion consisted of generalized and unsupported claims that they will assist in enforcement of the Act. Thus, the 1972 Interim Report states that the objects of the triplicate prescription provisions are to enable the Department of

* Hearings were held by the Temporary State Commission to Evaluate the Drug Laws which issued interim reports in 1971 (Ex. 31) and 1972 (Ex. 32, pp. 96-134). In addition, shortly prior to passage of the bill by the Legislature, Chester R. Hardt, Chairman of the Temporary State Commission, issued a memorandum (Ex. 33). It has been stipulated that, for purposes of this action, these three documents constitute the legislative history of the Act (Ex. 30).

Health "to compile data which will uncover irregularities such as forgeries, fraudulent obtaining of Schedule II substances, and theft of prescription blanks and their misuse by unauthorized persons" and to enable the Department to determine "if a patient has obtained prescriptions by going from doctor to doctor, or if stolen prescriptions are being used" and "where there has been an over-prescribing or over-dispensing of Schedule II drugs" (Ex. 32, p. 21). The Hardt Memorandum states that the triplicate prescription procedure is designed to reveal "physicians who have prescribed and dispensed a greater amount of a Schedule II substance than could possibly be justified by the nature of their practice" and "situations arising from lost or stolen prescriptions" (Ex. 33, p. 4).

The evidence in this case, as detailed below, shows that, to the extent they suggest that patients' names are needed, such claims are baseless; that over-prescription, over-dispensing of drugs and abuses resulting from thefts and forgeries of prescription blanks can all be detected equally well without centralized filing of patients' names; and that the sole remaining abuse cited, the obtaining of illicit amounts of drugs by going from "doctor to doctor" is minimal. These facts were not considered by the legislature. Indeed, the drafters of the Act never considered any of the following questions: whether accomplishment of the foregoing objectives could be achieved equally well without the patients' names; whether the patient's identity is actually required in any instance; and, if so, whether the abuse cited is sufficiently wide-spread to warrant the collection of data on 125,000 patients per month or 1.5 million prescriptions containing patients' names per year.

The answers to these questions (as contained in the evidence in this case) demonstrate the complete absence of any need for patients' names.

ARGUMENT

The Questions Raised by Appellant Are So Unsubstantial as Not to Warrant Further Argument.

1. *Plaintiffs Herein Clearly Have Standing to Sue.*

Preliminarily we note that the issue of standing—which now appears to be the principal ground upon which appellee seeks reversal of the decision below—was not even raised by appellee until the submission of post-trial briefs.

However, both the Court of Appeals when it directed that a three-judge court be convened and the three-judge court when it denied appellees' motion for a preliminary injunction clearly held that plaintiffs had standing to bring the instant action. Thus, the three-judge court stated (364 F.Supp. at 540, n.6):

"6. The physicians are not here merely asserting the rights of their patients but claim independent violations of protected constitutional rights. *Their standing to sue is established by Doe* v. *Bolton,* 410 U.S. 179, 93 S.Ct. 739, 35 L.Ed.2d 201 (1973). *See also, Roe* v. *Ingraham,* 480 F.2d 102 (2d Cir. 1973), at n. 5. Although it is unclear from the complaint, the Physicians Guild is apparently suing on behalf of its doctor members. Inasmuch as its claims are only repetitive, we may assume proper standing exists. Griswold v. Connecticut, 381 U.S. 479, 85 S.Ct. 1678, 14 L.Ed.2d 510 (1965), NAACP v. Alabama, 357 U.S. 449, 78 S.Ct. 1163, 2 L.Ed.2d 1488 (1958); Pierce v. Society of Sisters, 268 U.S. 510, 45 S.Ct. 571, 69 L.Ed. 1070 (1925)" (emphasis added).

And Justice Marshall stated in denying the State's application for a stay: "Likewise, the court's conclusion that respondents had standing seems in accord with the liberal standing decisions of this Court" (43a).

Nor can it seriously be disputed that the physicians and the patients who are plaintiffs herein have the required "personal stake in the outcome of the controversy," *Baker* v. *Carr,* 369 U.S. 186, 204 (1962); and that there is a "logical nexus between the status asserted and the claim sought to be adjudicated," *Flast* v. *Cohen,* 392 U.S. 83, 95 (1968).

The present statute interferes with the freedom of the physician plaintiffs to practice medicine according to the highest medical standard, *Doe* v. *Bolton,* 410 U.S. 179, 199 (1973); *Nyberg* v. *City of Virginia,* 361 F.Supp. 932, 936 (D.Minn. 1973), aff'd 495 F.2d 1342 (8th Cir. 1974). Thus, the *Roe* complaint alleges that the statute "infringes on the doctor's right to prescribe treatment for his patients solely on the basis of medical considerations" (Compl., par. 11). And the uncontradicted record proof in this case is that a plaintiff psychiatrist terminated the use of Schedule II drugs which he deemed helpful to patients suffering from certain psychiatric disorders because the fears created by the filing requirement would undermine the patient's trust and confidence in the psychiatrist (Tr. 45-60, 49), and that it became impossible for several physician plaintiffs to use Schedule II drugs in treating patients who needed such drugs after patients learned of the filing requirements (Tr. 68-72, 77-8, 104-5).

A further basis for the standing of the physician plaintiffs is that the physician is the one against whom the license revocation sanctions of Article 33 operate if he pre-

scribes or dispenses Schedule II drugs without causing a prescription form containing the patient's name to be filed in Albany (§ 3390(2)). See *Doe* v. *Bolton,* 410 U.S. 179, 188-9 (1973); *Abele* v. *Markle,* 452 F.2d 1121 (2d Cir. 1971); *Nyberg* v. *City of Virginia,* 361 F.Supp. 932, 936 (D. Minn. 1973), *aff'd* 495 F.2d 1342 (8th Cir. 1974). Here, as in *Doe* v. *Bolton, supra,* there is, thus, a "sufficiently direct threat of personal detriment" (410 U.S. at 188).

The facts that the patient plaintiffs have not suffered economic injury and that many other persons are also injured do not deprive them of standing. *United States* v. *SCRAP,* 412 U.S. 669, 686 (1973). In the *SCRAP* case, the injury alleged was that the failure of the Interstate Commerce Commission to suspend a 2.5% rate increase might adversely affect plaintiffs' "use and enjoyment of the natural resources of the Washington area" (p. 687). This Court summarized the "attenuated line of causation to the eventual injury" alleged by plaintiffs as follows (p. 688):

> "Here the Court was asked to follow a far more attenuated line of causation to the eventual injury of which the appellees complained—a general rate increase would allegedly cause increased use of nonrecyclable commodities as compared to recyclable goods, thus resulting in the need to use more natural resources to produce such goods, some of which resources might be taken from the Washington area, and resulting in more refuse that might be discarded in national parks in the Washington area."

Nevertheless, this Court held that plaintiffs had standing and explained its earlier holding in *Sierra Club* v. *Morton,* 405 U.S. 727 (1972) as follows (at pp. 686-7):

> "Nor, we said, could the fact that many persons shared the same injury be sufficient reason to disqualify from seeking review of an agency's action any person who had in fact suffered injury. Rather, we explained: 'Aesthetic and environmental well-being, like economic well-being, are important ingredients of the quality of life in our society, and the fact that particular environmental interests are shared by the many rather than the few does not make them less deserving of legal protection through the judicial process.' Id., at 734."

And further (p. 689, fn. 14):

> "The Government urges us to limit standing to those who have been 'significantly' affected by agency action. But, even if we could begin to define what such a test would mean, we think it fundamentally misconceived. 'Injury in fact' reflects the statutory requirement that a person be 'adversely affected' or 'aggrieved,' and it serves to distinguish a person with a direct stake in the outcome of a litigation—even though small—from a person with a mere interest in the problem. We have allowed important interests to be vindicated by plaintiffs with no more at stake in the outcome of an action than a fraction of a vote, see Baker v. Carr, 369 U.S. 186; a five-dollar fine and costs, see McGowan v. Maryland, 366 U.S. 420; and a $1.50 poll tax, Harper v. Virginia Bd. of Elections, 383 U.S. 663. While these cases were not dealing specifically with §702 of the APA, we see no reason to adopt a more restrictive interpretation of 'adversely affected' or 'aggrieved.' As Professor Davis has put it: 'The basic idea that comes out in numerous cases is that an identifiable trifle is enough for standing to fight out a question of principle; the trifle is the basis for standing and the principle supplies the motivation.' Davis, Standing: Taxpayers and Others, 35 U. Chi. L. Rev. 601, 613. See also K. Davis, Administrative Law Treatise §§22.09-5, 22.09-6 (Supp. 1970)."

Here, the patient plaintiffs are aggrieved in a direct, substantial and specific manner. Their right to private medical advice is not infringed by any "attenuated line of causation" such as the Court referred to in the *SCRAP* case. The challenged provisions of the Act, by requiring that a prescription form be filed with the State which contains, *inter alia,* the patient's name, address, age, medication and physician, clearly and directly invade the patient's privacy, causing the patient plaintiffs, all of whom are already in need of medical assistance, considerable additional stress and harm.

In *California Bankers Assn.* v. *Shultz,* 416 U.S. 21 (1974), a majority of this Court indicated that a broad requirement (such as the one at issue in the present case) of production of documents that "touch upon intimate areas of an individual's personal affairs" pursuant to a legislative scheme "which permits access to this information without invocation of the judicial process" would unconstitutionally invade the individual's privacy (416 U.S. at 78-79).

In *Shultz,* several individual bank customers (the "depositor plaintiffs"), banks (the "bank plaintiffs") and others contended that the delegation to the Secretary of the Treasury under the Bank Secrecy Act of broad authority to require reports of domestic monetary transactions from the financial institutions and parties involved was an unconstitutional invasion of privacy. Noting that despite the broad authority granted to the Secretary of the Treasury, the implementing regulations thereunder required only that the financial institution file a report on each domestic transaction in currency of more than $10,000 (31 C.F.R. §103.22), this Court held that the Act, as implemented by the regulations, did not unconstitutionally invade the bank plaintiffs' privacy (416 U.S. at 63-7).*

However, the concurring opinion of Mr. Justice Powell, with whom Mr. Justice Blackmun joined, made it clear that a majority of this Court (the two concurring and three dissenting justices**) would not have sanctioned the automatic production of large volumes of personal records without a summons or subpoena and without any showing of particularized need therefor.

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* The Court did not reach the question whether the depositor plaintiffs' privacy had been unconstitutionally infringed because there had been "no allegation by any of the individual depositors that they were engaged in the type of $10,000 domestic currency transaction which would necessitate that their bank report it to the government" (416 U.S. at 68). In this case, the allegations and proof were that every patient plaintiff except one used Schedule II drugs and thus prescriptions reflecting such use and his identity were being filed in Albany, and the one patient who no longer used Schedule II drugs had terminated such use rather than be subject to the filing requirements (Tr. 61-3).

** Justices Douglas and Marshall dissented in *Shultz* on the grounds, *inter alia,* that the domestic reporting provisions of the Bank Secrecy Act, even as narrowed by the regulations, constituted an invasion of privacy (see Douglas, J. at 416 U.S. at 87-91 and Marshall, J. at 93-99). Justice Brennan, who dissented on other grounds, found that "the reporting provisions are inseparable from —and in some cases considerably broader than—the record keeping requirements" (416 U.S. at 91) and did concur with the portions of Justice Douglas' opinion holding that the record keeping requirements violated the constitutional right of privacy (Douglas, J. at 416 U.S. at 79-86). Accordingly, we submit that it is fairly inferable that, at a minimum, Justice Brennan agreed with the concurring Justices that reporting requirements exceeding those embodied in the regulations promulgated under the Bank Secrecy Act would pose substantial and difficult constitutional questions.

In *Burrows* v. *Superior Court of San Bernardino County,* 118 Cal. Rptr. 166, 171 (1974), the California Supreme Court also concluded that the true meaning of *Shultz* was that it indicates that this Court will not uphold massive reporting requirements such as those authorized by but not implemented under the Bank Secrecy Act.

The concurring opinion stated (416 U.S. at 78-9):

> "The Act confers broad authority on the Secretary to require reports of domestic monetary transactions from the financial institutions and parties involved. 31 U.S.C. §§1081 and 1082. The only implementing regulations, however, require only that the financial institution 'file a report on each deposit, withdrawal, exchange of currency or other payment or transfer, by, through, or to such financial institution, which involves a *transaction in currency of more than $10,000.*' 31 CFR §103.22 (italics added). As the Court properly recognizes, we must analyze plaintiffs' contentions in the context of the Act as narrowed by the regulations. *Ante,* at 64. From this perspective, I agree that the regulations do not constitute an impermissible infringement of any constitutional right.
>
> "A significant extension of the regulations' reporting requirements, however, would pose substantial and difficult constitutional questions for me. *In their full reach, the reports apparently authorized by the open-ended language of the Act touch upon intimate areas of an individual's personal affairs.* Financial transactions can reveal much about a person's activities, associations, and beliefs. *At some point, governmental intrusion upon these areas would implicate legitimate expectations of privacy. Moreover, the potential for abuse is particularly acute where, as here, the legislative scheme permits access to this information without invocation of the judicial process.* In such instances, the important responsibility for balancing societal and individual interests is left to unreviewed executive discretion, rather than the scrutiny of a neutral magistrate. *United States* v. *U.S. District Court,* 407 U.S. 297, 316-317 (1972). As the issues are presently framed, however, I am in accord with the Court's disposition of the matter." (Emphasis added.)

The Act clearly touches upon "intimate areas of an individual's personal affairs." As Judge Friendly stated for the Second Circuit in reversing the order of dismissal of the District Court herein and directing that a three-judge court be convened (480 F.2d at 108, n. 7):

> "While the State correctly points out that the prescription form does not require a description of the illness, plaintiffs counter that, at least for some of the drugs in Schedule II, many members of the public know the ailments for which such drugs are commonly prescribed. To take perhaps the most obvious example, most informed people would associate large dosages of Demerol with an ailment causing serious pain. It is immaterial that the ailment usually is not one that should arouse any emotion toward the victim save sympathy; most people simply do not want their ailments to be generally known."

Similarly, this Court has held that included within the right of privacy is the right of anonymity. *N.A.A.C.P.* v. *Alabama,* 357 U.S. 449 (1958); *Talley* v. *California,* 362 U.S. 60 (1960); *Bates* v. *City of Little Rock,* 361 U.S. 516 (1960).

At the trial of this action, several patients indicated that the prospect of having their illnesses "generally known" by having them on file at a centralized state agency caused them acute discomfort and embarrassment. A post-operative cancer patient receiving Percodan to relieve his pain, first tried non-Schedule II drugs as substitutes (G. Patient 87) and when they did not yield satisfactory results, he obtained the required medicine in New Jersey where the information would not be put on a state-run computer (G. Patient 88). Another plaintiff, disregarding her doctor's advice, would not permit her son, who suffered from acute hyperkinesis, to continue receiving prescriptions for a Schedule II drug

after she learned that the prescription therefor, containing his identity, would be placed on the State's computer in Albany (Doe 61-3). Similarly, it hardly seems necessary to suggest that patients who suffer from ocular gyro-crises (involuntary upward rolling of the eyes; Tr. 28, 49-50) are distraught at the prospect of the centralized and easy access to information about their treatment. And all the other plaintiffs made it unmistakeably clear that they "simply do not want" information describing prescriptions which they or their children are required to take for entirely legitimate medical reasons to be filed with and computerized by the State (Moe 5-28; Poe 28-31; Martha Patient 31-36; Roe 102-3).*

Under these circumstances, we submit, the Court below was clearly correct in holding that plaintiffs herein had standing to sue.

2. *There Is No "Constitutionally Justifiable Pertinence" (410 U.S. at 197) for the State Statute Requiring Filing of Names of Patients Receiving Schedule II Drugs.*

The fundamental nature of the constitutional guarantee against invasion of privacy has been underscored by this Court's decisions in *Roe* v. *Wade,* 410 U.S. 113 (1973), *Doe* v. *Bolton,* 410 U.S. 179 (1973), and *California Bankers Assn.* v. *Shultz, supra.*

---

* For example, Mr. Moe testified that several physicians had advised him and his wife that their son "would have to take something like Ritalin for him to have any hope of having a normal childhood and learning" (Tr. 7) and his fear that "by the time my boy is an active citizen, there will be a long file on him in a narcotics or dangerous drug context, in which somebody can get a print-out and use it, once they have it, for whatever they use it for" (Tr. 14).

In *Roe* v. *Wade, supra,* this Court considered a Texas statute making it a crime to procure or attempt an abortion except "an abortion procured or attempted by medical advice for the purpose of saving the life of the mother" (410 U.S. at 118). The Court held that the statute violated the guarantee of privacy in the Due Process Clause of the Fourteenth Amendment to the extent that it unnecessarily restricted a woman's qualified right to terminate her pregnancy.

In setting forth the fundamental nature of the right of privacy, the Court stated (410 U.S. at 152-3):

> "The Constitution does not explicitly mention any right of privacy. In a line of decisions, however, going back perhaps as far as Union Pacific R. Co. v. Botsford, 141 U.S. 250, 251 (1891), the Court has recognized that a right of personal privacy, or a guarantee of certain areas or zones of privacy, does exist under the Constitution. In varying contexts the Court or individual Justices have indeed found at least the roots of that right in the First Amendment . . . ; in the Fourth and Fifth Amendments . . . ; in the penumbras of the Bill of Rights . . . ; in the Ninth Amendment . . . ; or in the concept of liberty guaranteed by the first section of the Fourteenth Amendment . . . . These decisions make it clear that only personal rights that can be deemed 'fundamental' or 'implicit in the concept of ordered liberty,' . . . are included in this guarantee of personal privacy. They also make it clear that the right has some extension to activities relating to marriage . . . , procreation . . . , contraception . . . , family relationships . . . , and child rearing and education . . . ." [Citations omitted.]

After noting that the right of privacy is "founded in the Fourteenth Amendment's concept of personal liberty" (410 U.S. at 153), the Court further held that an invasion of the

fundamental right of privacy can only be justified by a compelling state interest (410 U.S. at 155-6):

> "Where certain 'fundamental rights' are involved, the Court has held that regulation limiting these rights may be justified only by a 'compelling state interest,' *Kramer* v. *Union Free School District,* 395 U.S. 621, 627 (1969); *Shapiro* v. *Thompson,* 394 U.S. 618, 634 (1969), *Sherbert* v. *Verner,* 374 U.S. 398, 406 (1963), and that legislative enactments must be narrowly drawn to express only the legitimate state interests at stake. *Griswold* v. *Connecticut,* 381 U.S. at 485; *Aptheker* v. *Secretary of State,* 378 U.S. 500, 508 (1964); *Cantwell* v. *Connecticut,* 310 U.S. 296, 307-308 (1940); see *Eisenstadt* v. *Baird,* 405 U.S. at 460, 463-464 (White, J., concurring in result).
>
> "In the recent abortion cases, cited above, courts have recognized these principles. Those striking down state laws have generally scrutinized the State's interest in protecting health and potential life, and have concluded that neither interest justified broad limitations on the reasons for which a physician and his pregnant patient might decide that she should have an abortion in the early stages of pregnancy. Courts sustaining state laws have held that the State's determinations to protect health or prenatal life are dominant and constitutionally justifiable."

Noting that "the medical data indicating that abortion in early pregnancy, that is, prior to the end of the first trimester, although not without its risk, is now relatively safe" (410 U.S. at 149) and indeed "until the end of the first trimester mortality in abortion may be less than mortality in normal childbirth" (410 U.S. at 163), this Court concluded that the State's interest in preservation and protection of maternal health was not sufficiently compelling to warrant interference of the State with the decision by

the attending physician, in consultation with his patient, that the patient's pregnancy should be terminated.

In *Doe* v. *Bolton, supra,* this Court considered three procedural conditions precedent to an authorized abortion set forth in a Georgia statute. They were (1) that the abortion be performed in a hospital accredited by the Joint Commission on Accreditation of Hospitals; (2) that the procedure be approv[illegible] by the Hospital Staff Abortion Committee; and (3) that the performing physician's judgment be confirmed by the independent examinations of the patient by two other licensed physicians. The Court held that these provisions violated the Fourteenth Amendment because there was no "constitutionally justifiable pertinence" of the foregoing statutory requirements to the State's interest in protecting maternal health.

Thus, in holding that the interposition of the hospital abortion committee was unduly restrictive of the patient's right to privacy, the Court stated (p. 197):

> "Viewing the Georgia statute as a whole, *we see no constitutionally justifiable pertinence in the structure for the advance approval by the abortion committee.* With regard to the protection of potential life, the medical judgment is already completed prior to the committee stage, and review by a committee once removed from diagnosis is basically redundant. We are not cited to any other surgical procedure made subject to committee approval as a matter of state criminal law. The woman's right to receive medical care in accordance with her licensed physician's best judgment and the physician's right to administer it are substantially limited by this statutorily imposed overview." (Emphasis added.)

Appellant urges that "[t]he need for filing and patient identity was determined by the legislature" and suggests

that the Court below held that the problem of drug abuse was "beyond the power of the legislature to address itself to" (Jurisdictional Statement, pp. 16, 17). The contention is invalid and the suggestion incorrect. A legislative determination of "need" cannot immunize a statute from being held unconstitutional. As this Court stated in *Kedroff* v. *St. Nicholas Cathedral,* 344 U.S. 94, 106-107 (1952): "Certainly a legislature is free to act upon such information as it may have as to the necessity for legislation. But an enactment by a legislature cannot validate action which the Constitution prohibits, and we think the statute here in question passes the constitutional limits." Accord: *Harman* v. *Forssenius,* 380 U.S. 528, 542-543 (1965); *American Communic. Ass'n.* v. *Douds,* 339 U.S. 382, 400 (1950); *Doe* v. *Bolton, supra* at 197.

Nor did the Court below hold that the problem of drug abuse was beyond the power of the legislature to address itself to. The holding of the three-judge court herein that the statutory requirement of centralized patient name filing is unconstitutional was based upon its findings that the State's interest in controlling drug abuse was not served in any significant respect by the challenged provisions. Thus, the Court stated (11a):

> "Concededly the state effort to control drug abuse and to prevent illicit trafficking in dangerous drugs fosters a legitimate state purpose, and ordinarily we would be reluctant to interfere. The regulatory scheme, however, has a needlessly broad sweep. The state prescription form program provides for issuing serially numbered prescription forms to physicians. Each doctor prescribing and each pharmacist dispensing any Schedule II drugs are given a DEA number. They, therefore, are readily identifiable. The state can promptly determine the quantity of drugs prescribed and dispensed by particular physicians and pharmacists. Over-prescribing or dispensing, forgeries and thefts can be detected. Having the name of the person receiving the drugs on the state's form adds nothing. Indeed, admittedly the only purpose this information serves is to identify individual patients who without using an alias go from doctor to doctor to secure Schedule II drugs and those individuals who secure more than a 30-day supply in any single month. During the 20-month life of the program only one such unresolved incident in this category had been unearthed. The diminution of a constitutionally guaranteed freedom is too great a price to pay for such a small governmental yield." (Footnote omitted.)

The record herein fully supports the above findings and demonstrates that the State cannot point to *any* enforcement purpose that will be served by having patients' names recorded on the prescriptions and on the central computer in Albany and that the purposes for which Article 33 was enacted would be served equally well by legislation providing for the filing of the prescription without the patient's name.

For example, evidence adduced at the trial herein showed that printouts now being produced by the system enable the Department of Health to ascertain the average amount of each Schedule II controlled substance that is prescribed per physician (Ex. 14) and enable the State to go directly to those doctors who prescribe substantially more than the average to determine if there is a *bona fide* medical reason therefor (Cannizzaro 140-43). Another printout shows lost or stolen prescription blanks which have been cashed (Ex. G; Cannizzaro 143-4). Other printouts such as those showing two prescriptions with the same number and incorrect DEA numbers for doctors help detect forgeries (Ex. 16;

Cannizzaro 146-47). In addition, other printouts set forth the volume and frequency of the use of various drugs (Ex. 15; Cannizzaro 144-46).

None of the above printouts contains patient names. None of the legitimate and beneficial purposes of Article 33 served by these printouts are affected by the holding that the provisions of Article 33 requiring centralized filing of patients' names violate the Due Process Clause of the Fourteenth Amendment.

The principal claim of need for the statute has always been that the patient identification provisions are needed to investigate three categories of violations. When this case was before the Second Circuit, Judge Friendly summarized defendant's contentions and set forth the three categories as follows (480 F.2d at 108):

> "New York has advanced powerful arguments in support of the requirement of central filing of prescriptions for Schedule II drugs. The *most important* are that only by such filing, now complemented by the computer's ability to answer appropriate inquiries, can the State readily detect a number of serious abuses —the same patient going from doctor to doctor and thereby obtaining quantities of Schedule II drugs greater than his legitimate medical needs; overprescription by doctors; and the theft or forgery of prescriptions." (Emphasis added.)

On remand, the three-judge court denied the motion for a preliminary injunction and held that the issue of need was the "critical question" of this case (364 F.Supp. at 546):

> "The critical question is whether the objective which the regulation seeks to accomplish is necessitated by

> a subordinating state interest justifying the degree and consequences of the resulting personal intrusion."

Accordingly, it directed plaintiffs to "submit the necessary intensive and detailed analysis of the interests of the state and the individual", including specifically a demonstration "that the computerization of names is not necessary for the accomplishment of the state's goals (364 F.Supp. at 546).

Not only did plaintiffs submit such an analysis but the State *withdrew* its argument (previously cited to the Court of Appeals and the three-judge Court as the *raison d'etre* for the challenged provisions) that patients' names are required to detect the alleged "abuses" sought to be controlled by the Act.

Thus, in the Stipulation of Facts herein (based upon extensive prior discovery) the State conceded that its sole "need" for patients' names was to aid in detecting cases of persons who had gone "from doctor to doctor" to obtain excessive amounts of a Schedule II drug. Moreover, the State conceded, the patient's name is only of use if, going from doctor to doctor, the patient uses the same name. Thus, the State stipulated as follows (par. 12):

> "The only information from the computer which Dr. Baker [Associate Commissioner of the New York State Department of Health and the person charged with over-all responsibility for the triplicate prescription program] contemplates would contain the names of any patients is a print-out of patients who have obtained more than a 30-day supply of a Schedule II drug in a 30-day period. The only reason given by Dr. Baker for the above print-out is that it will assist in the identification and investigation of persons who,

using the same name, go from doctor to doctor to obtain an illicit supply of Schedule II drugs" (emphasis added).

In addition, Dr. Arthur G. Baker so testified in this case (Ex. 37, p. 139):

> "Q. Really we come back to what we said before, and that is the only reason why you have requested that the patient's name be put on the computer is to detect patients who go from doctor to doctor in order to obtain an excessive amount of a particular drug.
> A. That's correct."

Thus, in arguing to this Court that the decision below "ignored the use of filed prescriptions containing patient identity in checking on forgeries and raised prescriptions" (Jurisdictional Statement, p. 17),* the State has conveniently forgotten the evidence in this case summarized above including the above-quoted testimony of Dr. Baker and its own Stipulation in this case. The fact is that by the time of the trial herein, the State had (a) withdrawn the arguments made to the Second Circuit that the patient-identification provisions are needed to detect "over-prescriptions," "thefts," and "forgeries," (b) conceded that it did *not* need patients' names to solve any of those prob-

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* The further suggestion that filed patients' names are of use "in disciplinary proceedings" (Jurisdictional Statement, p. 17) was not made to the Court of Appeals or to the three-judge court below, and is totally devoid of record support. In addition, it makes no sense. Disciplinary proceedings are taken against doctors, not patients. As the system presently operates (i.e., after the decision of the court below), the prescriptions are still filed but with the patient's name deleted. Thus, the doctors' and pharmacists' names still appear on the prescription filed in Albany and, if the names of particular patients are required, they can be obtained from the pharmacist who filled the prescription and/or from the file of the doctor himself.

lems and (c) stipulated that the only need for patients' names was to aid in detecting instances of the so-called "doctor to doctor" situation alluded to by the Court of Appeals (Stip., par. 12). These concessions were based, *inter alia,* on the testimony of Dr. Baker that patients' names on the computer would not assist in detecting forgeries or raised prescriptions or thefts because the patient information on such prescriptions would be erroneous anyway (Ex. 37, pp. 118-21, 126-29). This evidence formed the basis for the conclusion of the three-judge court quoted above (*supra,* pp. 22-23).

In addition to the inherent improbability of persons going from doctor to doctor using their own names to obtain illegal amounts of drugs, there was overwhelming proof that the so-called problem of persons going from "doctor to doctor" was spurious. Thus, the State stipulated that from January 1, 1969 to the time of its most recent information there had been only four case reports of "doctor to doctor" type violations (Stip., par. 12), distributed as follows:

1974 — 1 case
1973 — None
1972 — None
1971 — 1 case
1970 — 1 case
1969 — 1 case

Indeed, although the State's Trial Memorandum stated that Mr. Cannizzaro, the state official in charge of processing the triplicate prescriptions, would testify "that the computer indicates that there are hundreds of persons, using the same name, receiving Schedule II drugs from more than one doctor, i.e., shopping" (Deft's Trial Memo., p. 10), there was in fact no such testimony and no evidence

that additional cases of patients going from doctor to doctor were referred to The Bureau of Narcotic Control. On the contrary, Cannizzaro testified that he had no knowledge of a single prosecution or arrest of a person shown by the computer to have obtained an illicit supply of Schedule II drugs by going "from doctor to doctor" (Cannizzaro 79-80).

Moreover, from the time of the inception of the system to the time of trial—a period variously put at twenty months (11a) and fifteen months (Jurisdictional Statement, p. 14)—there were only two reported cases involving a potential "doctor to doctor" problem. One investigation disclosed a *bona fide* patient relationship and the other was still pending at the time of trial (Stip., par. 15).

Finally, neither the Federal government in the Federal Drug Abuse Control Act (21 U.S.C. §§ 801 *et seq.*), the Commissioners on Uniform State Law in the Uniform Controlled Substances Act or the legislatures of 36 of the 40 states which have enacted statutes based on the Uniform Act found it "necessary" to require that the names of patients receiving Schedule II drugs be filed with a centralized agency.* The absence of provisions in parallel statutes by other legislatures has often been recognized as a prime factor indicating lack of need for such provisions. See e.g., *Doe* v. *Bolton, supra* at 194; *Harman* v. *Forssenius,* 380 U.S. 528, 542-543 (1965).

Defendant has argued at length that "defendant always had access to prescriptions, even before the passage of the statute involved" (Jurisdictional Statement, p. 13) and that plaintiffs "conceded . . . the constitutionality of the

* The statutes referred to are set forth in Appendix A to the memorandum filed by Appellees Roe, et al. in oposition to the stay for which the State applied to Mr. Justice Marshall.

prior law which allowed access to prescriptions by defendant's enforcement agents" (Jurisdictional Statement, p. 18).

Plaintiffs herein do not contend that the retention by a pharmacist of a copy of a prescription for a statutory period such as five years is an unreasonable diminution of their expectation of privacy. Plaintiffs neither concede nor reach the question whether prior New York State law (which apparently permitted a state investigator to obtain access to such documents without a warrant) was constitutional.* But we do submit that there is a world of difference between permitting an inspector access to records in the course of an investigation and requiring all pharmacies and doctors to turn over all such information *automatically* to the State. The old system was, by its very nature, a guarantee of reasonable privacy. The automatic collection of vast volumes of personal data by a centralized state agency obviously creates a far greater likelihood of invasion of privacy. One breach of security results in exposure of private information as to *all* listed patients. There was substantial and uncontradicted evidence before the Court below that the security of the State's computer facility was totally inadequate and that there was a substantial risk of unauthorized disclosure of the triplicate prescription information maintained there (Wasserman 1-65).

* As indicated by *California Bankers Assn.* v. *Shultz, supra; Burrows* v. *Superior Court of San Bernardino County, supra; Camara* v. *Municipal Court,* 387 U.S. 523 (1967); *See* v. *City of Seattle,* 387 U.S. 541 (1967); *Collonade Catering Corp.* v. *United States,* 397 U.S. 72 (1970); and *United States* v. *Bissell,* 406 U.S. 311 (1972), this is a substantial and difficult question which plaintiffs never intended to "concede" as the Court below suggested in its earlier opinion (see 364 F.Supp. at 544) and defendant continues to urge to this Court (Jurisdictional Statement, p. 18).

The Court below recognized that the development of modern methods of computerization of records, affording state investigators instant access to enormous volumes of personal information, poses a new and greater threat to privacy with which the courts must keep pace (12a). As the California Supreme Court observed in *Burrows* v. *Superior Court of San Bernardino County,* 118 Cal.Rptr. 166, 171 (1974):

> "Cases are legion that condemn violent searches and invasions of an individual's right to the privacy of his dwelling. The imposition upon privacy, although perhaps not so dramatic, may be equally devastating when other methods are employed. Development of photocopying machines, electronic computers and other sophisticated instruments have accelerated the ability of governments to intrude into areas which a person normally chooses to exclude from prying eyes and inquisitive minds. Consequently judicial interpretations of the reach of the constitutional protection of individual privacy must keep pace with the perils created by these new devices.[4]

[4] Back in 1890, Samuel Warren and Louis Brandeis, in their celebrated article, The Right to Privacy (4 Harv.L.Rev. 193, 195) foresaw this problem. They wrote: 'Recent inventions and business methods call attention to the next step which must be taken for the protection of the person, and for securing to the individual what Judge Cooley calls the right "to be let alone." Instantaneous photographs and newspaper enterprises have invaded the sacred precincts of private and domestic life; and numerous mechanical devices threaten to make good the prediction that what is whispered in the closet shall be proclaimed from the house-tops.' (Fn. omitted.)"

More "efficient" and therefore more threatening intrusions into privacy have already been subjected to greater constitutional restraints. For example, evidence obtained

by warrantless bugging is inadmissible (*Katz* v. *United States,* 389 U.S. 347 (1967)) while evidence obtained by warrantless listening outside an apartment door is admissible. *United States* v. *Ortega,* 471 F.2d 1350, 1361 (2d Cir. 1972), *cert. denied* 411 U.S. 948 (1973).

Moreover, because the records are obtained automatically without even a request by a state agent or the issuance of a warrant by a court, the present statute is particularly threatening. Unlike the Bank Secrecy Act at issue in *Shultz,* the filing provisions of the New York Public Health Law are "self-executing" (cf. 416 U.S. at 64). In *Shultz,* as this Court pointed out, the records "were to be available only by normal legal process . . . ." (416 U.S. at 54.) In sharp contrast, under the Act here challenged (1) there is no requirement that an administrative summons, subpoena or warrant be issued nor (2) must the records turned over be claimed to be relevant and material to a specific matter then under inquiry nor (3) is inspection by the State limited to a small number of persons. The Act explicitly provides that huge volumes of personal records be turned over *automatically* by every doctor and pharmacist in the State who prescribes or dispenses Schedule II medications.

CONCLUSION

The State has failed to demonstrate any need ("compelling" or otherwise) which justifies its system of continued monitoring of persons who take Schedule II drugs under the supervision of licensed physicians, for no reason other than to relieve pain and mitigate the effects of serious disease. On the contrary, the uncontradicted record proof in this case shows that the centralized collection of patients' names is not necessary or even appropriate to detect over-prescribing physicians, over-dispensing pharmacists or individuals who forge or steal prescription blanks. And as to individuals who supposedly go from "doctor to doctor" to obtain excessive amounts of Schedule II drugs (which persons, the State continues to assert, its system will aid in detecting), the record proof is also uncontradicted that such cases have been utterly insignificant historically (4 cases in the 7 years prior to trial) and have continued to be *de minimis* since institution of the present system (2 case reports referred for investigation).

We submit that Article 33's filing provisions violate the reasonable expectations of thousands of citizens that they may keep to themselves the nature of their treatment and illnesses and may maintain the confidentiality of communications with their physicians. There is and can be no reasonable basis for suspecting the overwhelming majority of persons utilizing Schedule II drugs or for prying into their personal affairs. The suggestion that the State has a security system which will preserve the confidentiality of such information is belied by the evidence in this case as well as by the innumerable examples of leaks of supposedly confidential information at all levels of our government.

We urge that the State's system is a totally unjustified intrusion into what Justice Brandeis described in his dissent in *Olmstead* v. *United States,* 277 U.S. 438, 478 (1928), as "the right to be let alone—the most comprehensive of rights and the right most valued by civilized men."

For the reasons set forth above and based upon the evidence adduced at trial, appellees submit that this Court should affirm the final order and judgment of the Court below permanently enjoining enforcement of, and declaring unconstitutional, those provisions of Article 33 of the New York Public Health Law which require physicians to record the identity of their patients on copies of prescription forms filed with the State.

Respectfully submitted,

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Supreme Court, U. S.
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IN THE

Supreme Court of the United States

OCTOBER TERM, 1975

No. 75-839

ROBERT P. WHALEN, as Commissioner of Health of the State of New York,

Appellant,

—against—

RICHARD ROE, an Infant, by ROBERT ROE, his Parent; JOHN DOE, an Infant, by MARY DOE, his Parent; JAMES MOE, an Infant, by MICHAEL MOE, his Parent; JANE POE, MATTHEW T. BRODY, ISRAEL L. SCHMIERER and EMPIRE STATE PHYSICIANS GUILD, INC.,

Appellees,

—and—

GEORGE PATIENT, MARTHA PATIENT, GERALD L. LUSTIG and THE AMERICAN FEDERATION OF PHYSICIANS AND DENTISTS,

Intervenor-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

MOTION TO AFFIRM

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In the

SUPREME COURT OF THE UNITED STATES

October Term, 1975

No. 75-839

ROBERT P. WHALEN, as Commissioner of the State of New York,

Appellant,

- against -

RICHARD ROE, et al.,

Appellees,

- and -

GEORGE PATIENT, et al.,

Intervenor-Appellees.

On Appeal from the United States District Court for the Southern District of New York

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MOTION TO AFFIRM

Intervenor-Appellees George Patient, et al., pursuant to Rule 16 of the Rules of this Court, move that the final judgment and decree of the District Court be affirmed on the grounds that the questions raised by the decision below are so insubstantial, and the decision below so plainly correct, as not to warrant further argument.

Preliminary Statement

This appeal is from a final judgment of a three-judge

court in the United States District Court for the Southern District of New York entered on October 9, 1975 which declared unconstitutional New York Public Health Law §§ 3331 (b), 3332(a) and 3333(4) insofar as they require the centralized filing of the names of patients receiving Schedule II prescription drugs. The opinion of that court is reproduced as Appendix "A" to the Appellant's Jurisdictional Statement.

Statute Involved

New York Public Health Law (P.H.L.) §§ 3331(6), 3332(2)(a) and 3333(4). These provisions require filing with the state all prescriptions for an entire category of drugs, which prescriptions must contain the patient's name and address. These provisions are:

P.H.L. § 3331(6):

> "6. A practitioner dispensing a substance which may be prescribed only upon an official New York state prescription must at the time of such dispensing prepare an official New York state prescription in the manner set forth in subdivision two of section thirty-three hundred thirty-two of this article. The practitioner shall retain one copy for five years and shall file

> the original and one copy with the department by not later than the fifteenth day of the next month following the month in which the substance was delivered. This requirement shall not apply to the dispensing by a practitioner pursuant to section thirty-three hundred fifty-two of this article."

P.H.L. § 3332(2)(a):

> "2. Such prescription shall be prepared in triplicate, writen [sic] in ink, indelible pencil or, apart from the practitioner's signature, typewriter. The original and both copies must contain the following:
>
> (a) the name, address and age of the ultimate user for whom the substance is intended, or, if the ultimate user is an animal, the species of such animal and the name and address of the owner or person in custody of such animal;"

P.H.L. § 3333(4):

> "4. The endorsed original prescription shall be retained by the proprietor of the pharmacy for a period of five years. The endorsed copy of such prescription shall be filed with the department by not later than the fifteenth day of the next month following the month in which the substance was delivered."

Other possibly relevant portions of Article 33 of the New York Public Health Law are set forth in appendix "D" to Appellant's Jurisdictional Statement.

Questions Presented

Appellant has raised two issues in its Jurisdictional Statement:

1. Did the Court below err in finding that plaintiffs have standing to sue or that they had presented a real case or controversy? (Jurisdictional Statement, p. 11)

2. Where the statute involves a fundamental right of privacy, did the federal court below err by reviewing a legislative finding of need with the view toward determining whether that legislative purpose was being sought by unconstitutional means? (Jurisdictional Statement, p. 16)

Statement of Case

This is an action for declaratory and injunctive relief to invalidate a state statute which requires all physicians, when prescribing a Schedule II drug (P.H.L. § 3306), to do so on a triplicate form, a copy of which must contain the name of the patient and must be filed with and computerized by the State Department of Health. The challenge is to the systematic collection and filing of information of a most confidential nature and to the massive breach by the state of the confidentiality of the doctor-patient relationship.

Plaintiffs Roe, et al., originally moved by order to show cause on March 29, 1973 in the Southern District of New York to prevent the implementation of the law. Immediately thereafter, plaintiff-intervenors Patient, et al., were granted leave to intervene and their action was consolidated into the initial action. On April 6, 1973 a single judge, Robert L. Carter, dismissed the

complaint based on a finding that the complaint failed to raise a substantial federal question. (357 F.Supp. 1217 (1973))

Appeal was taken to the Second Circuit Court of Appeals. There Judge Friendly, with Judges Hays and Jameson concurring, reversed Judge Carter, found that the complaint raised a substantial federal question, and remanded for consideration by a three-judge court. (480 F.2d 102 (1973))

A three-judge court consisting of Judges Feinberg, Wyatt and Carter was then convened and heard oral argument on Appellees' motion for a preliminary injunction and Appellant's renewed motion to dismiss. On August 23, 1973 it denied both motions. (364 F.Supp. 536 (1973))

The case was tried in December 1974 before the three judges, and in August 1975 that court found that the statute was unconstitutional and it enjoined further centralized reporting and filing of patient names.

Appellant, in October 1975, applied to Mr. Justice Marshall of this Court for a stay of the lower court order pending appeal. Reply papers were submitted by Appellees. Justice Marshall heard oral argument of all counsel and on October 28, 1975, in a written opinion, denied Appellant's application for a stay. A copy of that opinion is attached hereto as Appendix "A."

Lower Court Ruling

The Facts.

The three-judge court, in an opinion by Judge Carter

a copy of which is attached to the Appellant's Jurisdictional Statement, found that physicians prescribing Schedule II drugs were required to centrally file all such prescriptions -- including the name of the patient -- with the State Department of Health. The Department of Health took the approximately 100,000 such prescription forms received each month and, with the help of nine clerks and numerous personnel, computerized all of the names.* The Department's intended use of this material was (1) to identify persons using the same name who go from doctor to doctor or (2) to uncover those receiving more than a 30-day supply of drugs each month.**

The court found that this system had turned up <u>two</u> names over a period of one and one-half years:

> "Two such names have been discovered since the computerized program has been in operation. Both were referred to the BNC [Bureau of Narcotic Control] for investigation. In one case, the investigation disclosed a bona fide doctor-patient relationship, and in the other the investigation was still open when all evidentiary data was submitted for our consideration." (Opinion, p. 5a.)

The court found that the plaintiff-patients, upon learning of the new system, had substantially changed their pattern of medically-indicated drug use to their medical detriment. One parent had taken her child off a useful drug, which resulted

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* Opinion, p. 4a

** Opinion, p. (5a)

in reducing the child's effectiveness in school. Another suffered continuing fears of stigmatization as a drug abuser. Still another had stopped drug use, had been subject to physical suffering, and had been forced to resume use. Another patient went out of state to avoid the system.*

Four doctors testified that the system had an adverse effect on patients. One doctor refused to prescribe Schedule II drugs entirely, requiring patients to use drugs which were admittedly less effective.

> "All [doctors] testified that they felt obligated to advise their patients or a responsible member of their family about the state prescription program for Schedule II drugs and reported a reaction of shock, fear and concern on the part of their patients on learning that their names would be sent to Albany and put on a computer." (Opinion, p. 7a)

<u>The Holding</u>.

The Court was very much aware of the state's concern with drug use but found that the state program was unnecessarily sweeping:

> "Concededly the state effort to control drug abuse and to prevent illicit trafficking in dangerous drugs fosters a legitimate state purpose, and ordinarily we would be reluctant to interfere. The regulatory scheme, however, has a needlessly broad sweep." (Opinion, p. 11a)

Pointing out that prescriptions are written on serially numbered

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* Opinion, 6a

forms, the court concluded: "Having the name of the person receiving the drugs on the state's forms adds nothing." (Opinion, 11a)

Accordingly, the court found that the reporting requirement constituted "an unconstitutional interference with the plaintiffs' right of privacy . . ." (Opinion, 13a)

ARGUMENT

I

THE ISSUES OF LAW HAVE BEEN THOROUGHLY EXAMINED BY THE FEDERAL COURTS BELOW AND THE QUESTIONS RAISED ARE ADDRESSED TO THE SUFFICIENCY OF THE RECORD

The Appellant's Jurisdictional Statement attempts to imply that the court below gave standing to hypothetical plaintiffs and then applied new law on which to base relief. Nothing could be further from the truth.

In fact, the several courts below again and again demanded that these plaintiffs show injury and address themselves to the state need for the information sought. Judge Carter originally dismissed the complaint (347 F.Supp. 1217) on the basis of premature conclusions regarding state need and plaintiffs' injury -- conclusions arrived at before plaintiffs had had an opportunity to submit proof on the merits. Judge Friendly, in his opinion in the Second Circuit reinstating the complaint (480 F.2d 102), noted that the district court "was not entitled to dismiss the complaint on the basis of the State's assertions . . ." without "further exploration of the degree of need for central filing including

patients' names on the one hand, and the adequacy of the provisions to protect against malicious or careless disclosure on the other." 480 F.2d at 109. Judge Friendly emphasized throughout his opinion the plaintiff's burden of showing injury and of showing that that injury outweighed the state need. Both of these courts emphasized that plaintiffs must make a strong factual showing.

The requirement of proof, rather than "ingenuous pleadings,"* was again emphasized by the three-judge court when it denied plaintiffs' motion for a preliminary injunction. (364 F.Supp. 536) Again, the court required a showing, not made at that time, of damage to the plaintiffs resulting from the state's program. Absent such a showing, the court denied plaintiffs' request for relief.

Only after trial, after hearing patients and doctors, after examining voluminous depositions (submitted as part of the trial) relating to the need for, the use of, and the effect of the system, did the court below reach any conclusion favorable to the plaintiffs. After these findings of fact, set forth in detail in its opinion -- findings on the degree of need, findings on the degree of plaintiffs' damage, findings on the utility of the system -- did the court below find that the state had created a bludgeon to do the work of a scalpel. The court below rejected every invitation to apply broad, new principles of law, and placed the burden on these plaintiffs of demonstrating that the law as established by this Court when applied to the facts here compelled relief.

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* Appellant in his Jurisdictional Statement (pp. 15,20) relies upon United States v. SCRAP, 412 U.S. 669, 688 (1973) where this Court, in dicta, indicated that "ingenuous pleadings" alone cannot give standing. Appellant's implication that plaintiffs here are relying upon such pleadings is totally erroneous, as demonstrated infra.

The Appellant here does not so much challenge the legal conclusions of the court below but rather the factual conclusions, principally whether these plaintiffs were in fact injured. But the court below did not deal abstractly with this question. It took testimony, saw and heard plaintiff-patients and doctors. The court found, as a matter of fact, from the record after trial, that there was injury to the plaintiffs and that the state had alternative means to regulate unlawful conduct without subjecting every patient receiving medically-indicated drugs to state scrutiny. These were the court's findings. Having made these findings, the court then applied the law as prescribed by this Court. The Appellant's Jurisdictional Statement does not point to any ruling of this Court ignored or misapplied by the court below. Rather, the Appellant excepts to the conclusions of fact which the court below drew from the trial record. Appellant raises its exceptions through two issues set forth in its Jurisdictional Statement. The first is whether these plaintiffs had standing; the second is whether the court below could properly review the legislative determination that this system fulfilled a need and was thus permissible. Neither of these issues merits plenary consideration by this Court.

II

THE FINDING OF STANDING IS WELL WITHIN THE PAST HOLDINGS OF THIS COURT

Justice Marshall, upon denying a stay in this case,

and referring to the court below, wrote:

> "Likewise, the court's conclusion that respondents had standing seems in accord with the liberal standing decisions of this court."

Appellant's standing argument relies upon the assertion that the plaintiff-patients have simply asserted fears of consequences which have not happened and that those fears alone do not constitute a basis for standing. Appellant relies for this argument on the holding of Laird v. Tatum, 408 U.S. 1, 13-14 (1972) where the plaintiffs had been the subject of lawful public surveillance but had suffered no injury nor changed their behavior at all. Appellant also relies on the dismissal, in California Bankers Ass'n v. Schultz, 416 U.S. 21, 56-57 (1973), of a claim by the ACLU on behalf of its members that those members had a right not to have a bank keep records of their bank transactions for fear that the records might discourage conduct. In both Laird and Schultz the plaintiffs were simply members of the general public who could show no injury or change of conduct on their part in response to government conduct. These cases are readily distinguishable from the case at bar where proof at trial showed that the plaintiff-patients had in fact altered the medical treatment that they received. Additionally, doctor-plaintiffs had stopped prescribing the drugs in question; other doctors made adjustments in their practice to compensate for the shock or anxiety of patients and one doctor had actually stopped prescribing the drugs in question.

Appellant relies further on dicta in United States v. SCRAP, 412 U.S. 669, 688 (1973) which stated that imagined circumstances do not give a plaintiff standing.* But these plaintiffs have not "imagined circumstances." The court below found definite changed medical practice. Furthermore, in SCRAP this Court sustained a District Court holding that an environmental group did have standing, noting that they contended

> "their pleadings sufficiently alleged that they were 'adversely affected' or 'aggrieved' . . . and they point specifically to the allegations that their members used the forests, streams, mountains, and other resources in the Washington metropolitan area for camping, hiking, fishing, and sightseeing, and that this use was disturbed by the adverse environmental impact caused by the nonuse of recyclable goods brought about by a rate increase on those commodities. The District Court found these allegations sufficient to withstand a motion to dismiss. We agree." 412 U.S. at 685.

The recreational use of outdoor streams was found sufficient to give standing to challenge a 2.5% surcharge increase on railroad freight rates which might lead to a reduction of recycling of waste materials. This basis of standing was far more circuitous and remote than that advanced by the plaintiffs here.

The courts below and the Second Circuit were not trouble

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* "A plaintiff must allege that he has been or will in fact be perceptibly harmed by the challenged agency action, not that he can imagine circumstances in which he could be affected by the agency's action. And it is equally clear that the allegation must be true and capable of proof at trial." (412 U.S. at 688-689)

by the standing argument for a more simple reason: the regulation intrudes directly into the patients' relationships with their doctors. Judge Friendly, in an extensive opinion (480 F.2d 102 (1973)) concurred in by Judges Hays and Jameson, did not deal explicitly with the standing argument. But in his discussion of the privacy argument itself he recognized that the regulation directly affected that relationship for each of the patient-plaintiffs in this action. These patients had their names -- and drug use -- recorded and sent to Albany and filed centrally for random review by the state. Their private ailments as referred to by Judge Friendly at 480 F.2d 108, and their doctors' prescriptions relating to them were reported to the state. For this reason alone these plaintiffs fell well within the past standard of this Court set forth in Baker v. Carr:

> "Have the appellants alleged such a personal stake in the outcome of the controversy as to assure that concrete adverseness which sharpens the presentation of issues upon which the court so largely depends for illumination of difficult constitutional questions?" 369 U.S. 186, 204 (1962).

Do these plaintiff-appellees have a stake in the outcome here? As the many judges who have reviewed this case in the light of the applicable precedents have found, the answer is clearly "yes."

III

THE COURT BELOW APPROPRIATELY REVIEWED THE CONSTITUTIONALITY OF THE STATUTE

The Appellant next urges that the Legislature has made a finding of need for the legislation and that that need may not be reviewed by a federal court. At page 20 of the Jurisdictional Statement, the Appellant urges:

> "The Legislature determined the need for filing. Whether filing will achieve all the purposes envisioned by the Legislature is not the issue. Whether these hopes are achieved in the end does not affect the law's constitutionality. See James v. Strange, 407 U.S. 128, 133 (1972); Mourning v. Family Publications Service, Inc., 411 U.S. 356, 378 (1973).
>
> The question of the power of the Legislature is not to be confused with the scope of legislative considerations in dealing with a matter of policy. The District Court cannot indulge in a legislative judgment which it obviously did. Brotherhood of Locomotive Firemen & Enginemen v. Chicago R.I. & R.Rd. Co., 383 U.S. 128, 136 (1968); see also Cohen v. Beneficiary Finance Corp., 337 U.S. 541, 548-549 (1949).

The two cases relied upon for this position, Brotherhood, supra, and Cohen, supra, involve questions of the constitutionality of business regulation, an area self-evidently distant from the concerns of confidential information, the doctor-patient relationship, and the penumbra of privacy involved here.

Yet Appellant's Jurisdictional Statement is utterly devoid of any suggestion why this Court should suddenly discard in this case relevant and well-established standards relating to the

constitutional right of privacy. Rather, Appellant simply asserts that the Court should automatically show the same deference to legislative judgment here as it does in cases involving the regulation of corporate derivative suits (Cohen, supra) or railroad union practices (Brotherhood, supra).

The court below, and the Second Circuit in this case, discussed in great detail the substantial body of law developed by this Court relating to the right of privacy,* and properly applied that body of law to the case.

In Griswold v. Connecticut, 381 U.S. 479 (1965), this Court set forth the standard that in matters that are of a private nature the state may interfere with the individual's right of privacy only where it can show a compelling state interest. The means used must be:

> "necessary and not merely rationally related to the accomplishment of a permissible state policy." 381 U.S. at 497.

In subsequent cases involving doctors and patients, Eisenstadt v. Baird, 405 U.S. 438 (1972), Roe v. Wade, 410 U.S. 113 (1973), and Doe v. Bolton, 410 U.S. 179 (1973), this Court has recognized that the area of medical treatment and private

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* The lower court cited in its opinion (p. 8a) a string of cases going back 80 years: Union Pacific R.R. Co. v. Botsford, 141 U.S. 250 (1891); Meyer v. Nebraska, 262 U.S. 390 (1923); Pierce v. Society of Sisters, 268 U.S. 510 (1925); Kovacs v. Cooper, 336 U.S. 77 (1949); Griswold v. Connecticut, 381 U.S. 479 (1965); Loving v. Virginia, 388 U.S. 1 (1967); Katz v. United States, 389 U.S. 347 (1967); Stanley v. Georgia, 394 U.S. 557 (1969); Eisenstadt v. Baird, 405 U.S. 438 (1972); Roe v. Wade, 410 U.S. 113 (1973); Doe v. Bolton, 410 U.S. 179 (1973).

ailments is one that is most private. In the doctor-patient relationship, the patient has a strong expectation of privacy and that expectation is entitled to the most comprehensive protection.*

All of the courts below, including especially the three-judge court which considered the facts at trial, weighed carefully what they recognized to be "powerful arguments" of the state, 480 F.2d at 108, or a "legitimate state purpose" (Opinion of the three-judge court at 11a), but they also recognized that the state's power to regulate had to be scrutinized within the constitutional bounds of the right of privacy.**

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* In Doe this Court spoke of "the [patient's] right to receive medical care in accordance with her licensed physician's best judgment and the physician's right to administer it [410 U.S. at 197]. As the court below stated: "Justice Douglas had described the expectation of privacy in the doctor-patient relationship as being exceeded only by that expectation in the relationship of a penitent to his priest." 410 U.S. at 219 (Opinion, 9a)

** Judge Friendly gave framework to the case by citing the words of Justice Harlan in his dissent in Poe v. Ullman, 367 U.S. 497, 543 (1961):

> "the liberty guaranteed by the due process clause 'is a rational continuum which, broadly speaking, includes a freedom from all substantial arbitrary impositions and purposeless restraints, . . . and which also recognizes, what a reasonable and sensitive judgment must, that certain interests require particular careful scrutiny of the state needs asserted to justify their abridgement.'" 480 F.2d at 108.

In view of these holdings and the careful scrutiny which this Court has given to statutes regulating the doctor-patient relationship, it is at best bizarre for the Appellant to insist that the holdings in Brotherhood and Cohen, supra, relating to economic regulation, foreclose scrutiny of the statute in the instant case.

Furthermore, the court below was well within the most solid traditions of the law when it relied upon the well-established doctrine that regulation which invades areas of personal freedom must be narrowly drawn. N.A.A.C.P. v. Alabama, 377 U.S. 288, 307 (1964); Erznoznik v. City of Jacksonville, 95 S.Ct. 2268 (1975); Shelton v. Tucker, 364 U.S. 479, 488 (1960). The court pointed to this Court's standard in N.A.A.C.P. v. Button, 371 U.S. 415, 438 (1963) that where fundamental rights are involved, "precision of regulating must be the touchstone," a rule supported in the privacy area in Griswold, supra, which held that a regulation that infringes on the right to privacy must be necessary, and no more sweeping than required by that necessity.

This is precisely the tradition invoked by the lower court where it found that:

> "The regulatory scheme, however, has a needlessly broad sweep . . . Having the name of the person receiving the drugs on the state's form adds nothing." (Opinion, 11a)

and

> "The diminution of a constitutionally guaranteed freedom is too great a price to pay for such a small governmental yield." (Opinion, 11a)

In summary, there can be no doubt that a federal court may review a state statute which interferes with the doctor-patient relationship to test the constitutionality of that statute. The court below took testimony and reviewed the statute within the well-established standards of this Court. The questions raised by the Appellant therefore do not require the plenary consideration of this Court.

Conclusion

Based on the careful scrutiny of the court below, and the nature of the questions raised on this appeal, it is respectfully moved that this Court affirm the judgment below.

Dated: New York, New York
February 4, 1976

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APPENDIX

Appendix A, Opinion of Mr. Justice Marshall Denying Appellant's Application for Stay, October 28, 1975 (96 S.Ct. 164)

SUPREME COURT OF THE UNITED STATES

No A-368

Robert P. Whalen, Commissioner of Health of New York, Appellant, v. Richard Roe, an infant by Robert Roe, his parent, et al.	Application for Stay.

[October 28, 1975]

MR. JUSTICE MARSHALL, Circuit Justice.

This is an application for a stay of the judgment of a three-judge court sitting in the Southern District of New York. The applicant, the Commissioner of Health of the State of New York, has been enjoined by the three-judge court from enforcing certain provisions of New York's Public Health Law (the Law). Respondents are various physicians, organizations of physicians, and patients in the State of New York who successfully brought suit to have those provisions declared unconstitutional.

The provisions at stake are those parts of §§ 3331 (6), 3332 (2)(a), and 3334 (4) of the Law that require the name and address of each patient receiving a Schedule II controlled substance to be reported to the applicant. Schedule II drugs are those that have a high potential for abuse, but also have an accepted medical use. They include opiates and amphetamines. Under the state law, a doctor prescribing a Schedule II drug does so on a special serially numbered triplicate prescription form. One copy is retained by the doctor, a second goes to the pharmacist (if applicable), and the last copy goes to the applicant, who transfers the data, including the name

and address of the patient, from the prescription to a centralized computer file.

Respondents brought this action shortly after the effective date of the computerization program, alleging violations of their constitutional rights under 42 U. S. C. § 1983 and grounding jurisdiction on 28 U. S. C. § 1343 (3). Specifically, respondents claimed that mandatory disclosure of the name of a patient receiving Schedule II drugs violated the patient's right of privacy and interfered with the doctor's right to prescribe treatment for his patient solely on the basis of medical considerations. A three-judge court was convened. *Roe* v. *Ingraham*, 480 F. 2d 102 (CA2 1973).

At trial, various respondents testified that they were inhibited from using or prescribing Schedule II drugs they otherwise found beneficial because of a reluctance to disclose their or their patients' identities to the State. While questioning respondents' standing to sue, the State asserted that knowledge of patients' names was necessary to enable the computer system to detect drug abuse. When put to its proof by respondents, however, the State eventually conceded that the names and addresses of patients were useful in detecting only one abuse: patients who go from doctor to doctor (using the same name on each visit) in order to obtain an excess supply of drugs. Thereupon respondents showed that in 15 months of operation the computer system had located only one suspected "doctor-shopper" while processing over 125,000 prescriptions per month. Thus respondents contended that the centralization of patients' names and addresses served no compelling state interest sufficient to offset the asserted invasion of privacy.

The three-judge court accepted respondents' arguments. The court read our decisions in *Roe* v. *Wade*, 410 U. S. 113 (1973), and *Doe* v. *Bolton*, 410 U. S. 179 (1973), as placing the doctor-patient relationship among those zones of privacy accorded constitutional protection.

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While noting that *Roe* and *Doe* concerned the most intimate of personal relations, sexual intimacy and the decision to bear a child, the court refused to hold the doctor-patient relationship constitutionally protected only when matters of childbearing were at stake. Rather, it noted the intimate nature of a patient's concern about his bodily ills and the medication he takes, and held that these matters too are protected by the constitutional right to privacy. While reaching this conclusion primarily on the basis of *Roe* and *Doe*, the court drew some support from the concurring and dissenting opinions in *California Bankers Assn.* v. *Shultz*, 416 U. S. 21, 78, 79, 91, 93 (1974), which it read as indicating that a majority of this Court would accord constitutional protection, at least against a wholesale reporting requirement, to all "intimate areas of an individual's personal affairs." *Id.*, at 78 (POWELL, J., concurring). Upon finding that respondents had a protected privacy interest in the medication they received, the court balanced that interest against the State's need for patient names, and concluded that, with one suspect uncovered over 15 months, the need shown was ephemeral. "The diminution of a constitutionally guaranteed freedom is too great a price to pay for such a small governmental yield." *Roe* v. *Ingraham*, slip op., at 16 (footnote omitted).

Finding those portions of the Law that demanded disclosure of patients' names and addresses to the State to be unconstitutional on the facts, the court enjoined the State from enforcing those provisions and from accepting for filing prescriptions or other documents disclosing the identities of patients receiving Schedule II drugs. The court also ordered the destruction of any name-bearing prescription forms in the State's possession and the expungement of names from all computer records. The court stayed the destruction and expungement order pending disposition of the case by this Court; it refused,

however, to stay its declaration of unconstitutionality and its injunction against enforcement of the provisions and acceptance of incoming prescriptions.

Thus the application for stay now before me concerns only those matters the District Court refused to stay. The principles that govern a Circuit Justice's in-chambers review of stay applications are well known. A single Justice will grant a stay only in extraordinary circumstances. Certainly the judgment of the lower court, which has considered the matter at length and close at hand, and has found against the applicant both on the merits and on the need for a stay, is presumptively correct. To prevail here the applicant must meet a heavy burden of showing not only that the judgment of the lower court was erroneous on the merits, but also that the applicant will suffer irreparable injury if the judgment is not stayed pending his appeal.

MR. JUSTICE POWELL has succinctly stated the considerations pertinent to evaluating these two factors:

> "As a threshold consideration, Justices of this Court have consistently required that there be a reasonable probability that four members of the Court will consider the issue sufficiently meritorious to grant certiorari or to note probable jurisdiction. See *Mahan* v. *Howell*, 404 U. S. 1201, 1202; *Organized Village of Kake* v. *Egan*, 80 S. Ct. 33, 4 L. Ed. 2d 34 (1959). Of equal importance in cases presented on direct appeal—where we lack the discretionary power to refuse to decide the merits—is the related question whether five Justices are likely to conclude that the case was erroneously decided below. Justices have also weighed heavily the fact that the lower court refused to stay its order pending appeal, indicating that it was not sufficiently persuaded of the existence of potentially irreparable harm as a result of enforcement of its judgment in the interim." *Graves* v. *Barnes*, 405 U. S. 1201, 1203–1204 (1972) (POWELL, J., in chambers).

See also *Aberdeen & Rockfish R. Co.* v. *SCRAP*, 409 U. S. 1207, 1218 (1972) (BURGER, C. J., in chambers); *Railway Express Agency* v. *United States*, 82 S. Ct. 466, 7 L. Ed. 432 (1962) (Harlan, J., in chambers); *United Fuel Gas Co.* v. *Public Service Comm'n*, 278 U. S. 322, 326 (1929).

Applying these standards to the application before me, I conclude a stay should not be granted. The three-judge court gave careful consideration to applicant's motion for a stay and, indeed, granted one insofar as it deemed necessary to prevent irreparable harm to applicant's interests. Applicant has shown nothing to persuade me the lower court erred. If applicant's position is sustained on appeal, all the data it is precluded from processing by the District Court's order will be readily available from the State's doctors and pharmacists, who are required by law to retain the complete prescription form for five years. The information now denied the State's computers can thus be located and tabulated at a later date. While the State may suffer delay in the complete implementation of its computerization program, delay alone is not, on these facts, irreparable injury.

I conclude that applicant would suffer no irreparable injury if a stay is denied. This conclusion necessarily decides the application and renders unnecessary consideration of the possibility, since this case involves an appeal as of right, that applicant will be able to convince five Justices to reverse the three-judge court. I do note, however, that the right to privacy is a sensitive and developing area of the law and that the three-judge court did not apply it in a manner plainly inconsistent with our decisions. Likewise, the court's conclusion that respondents had standing seems in accord with the liberal standing decisions of this Court. Of course, this conclusion and my denial of a stay on the papers now be-

fore me is not to be taken as a reflection of my views on the merits of this case, or as an indication of the ultimate disposition of the case in this Court.

The application is denied.

Supreme Court, U. S.
FILED
MAY 21 1976
MICHAEL RODAK, JR., CLERK

Supreme Court of the United States

OCTOBER TERM, 1975

No. 75-839

ROBERT P. WHALEN, as Commissioner of Health of the State of New York,

Appellant,

against

RICHARD ROE, an infant by ROBERT ROE, his parent; JOHN DOE, an infant by MARY DOE, his parent; JAMES MOE, an infant by MICHAEL MOE, his parent; JOHN POE, MATTHEW T. BRODY, ISRAEL L. SCHMIERER AND EMPIRE STATE PHYSICIANS GUILD, INC.,

Appellees,

and

GEORGE PATIENT, MARTHA PATIENT, GERALD L. LUSTIG, and THE AMERICAN FEDERATION OF PHYSICIANS AND DENTISTS,

Intervenor-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

BRIEF FOR APPELLANT

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Supreme Court of the United States

OCTOBER TERM, 1975

No. 75-839

ROBERT P. WHALEN, as Commissioner of Health of the State of New York,

Appellant,

against

RICHARD ROE, an infant by ROBERT ROE, his parent; JOHN DOE, an infant by MARY DOE, his parent; JAMES MOE, an infant by MICHAEL MOE, his parent; JOHN POE, MATTHEW T. BRODY, ISRAEL L. SCHMIERER AND EMPIRE STATE PHYSICIANS GUILD, INC.,

Appellees,

and

GEORGE PATIENT, MARTHA PATIENT, GERALD L. LUSTIG, and THE AMERICAN FEDERATION OF PHYSICIANS AND DENTISTS,

Intervenor-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

BRIEF FOR APPELLANT

Opinions Below

Opinion of the District Court (single judge), denying motion to convene three-judge court and dismissing complaint is reported at 357 F. Supp. 1217 (3a).* Opinion of the Court of Appeals for the Second Circuit reversing the

* Numbers in parentheses refer to Appendix (a) or Appendix to Jurisdictional Statement (J.S. a).

order of the District Court and remanding for the convening of a three-judge court is reported at 480 F. 2d 102 (41a). The opinion and order of the three-judge court denying a preliminary injunction to appellees and also denying a motion to dismiss to appellant is reported at 364 F. Supp. 536 (57a). The opinion of the three-judge court granting judgment for appellee is reported at 403 F. Supp. 931 (J.S. 1a). The opinion of Justice Thurgood Marshall denying stay of District Court judgment. —— U.S. ——, 96 S. Ct. 164 (J.S. 39a).

Jurisdiction

Appellant invokes the jurisdiction of this Court pursuant to 28 U.S.C. § 1253. The judgment appealed from was entered October 9, 1975 (J.S. 14a). Notice of Appeal was filed October 20, 1975 (J.S. 18a). Probable jurisdiction was noted on February 24, 1976 (44 U.S.L.W. 3471).

Questions Presented

1. Does the statutory prescription filing requirement as contained in the Public Health Law (P.H.L.), Art. 33 invade any constitutionally protected right of privacy of the appellees?

2. Did the District Court apply the proper test of constitutionality in using the compelling state interest test or "fundamental right" standard as to the filing statute?

3. In any event under any test was the District Court correct in concluding that New York did not need patient identity on filed Schedule II prescription to achieve a legitimate state purpose?

4. Did the appellees have standing or present a real case or controversy in face of the strict confidentiality provisions in the law?

Statement

The judgment appealed from was entered in two actions seeking declaratory and injunctive relief. They were brought to invalidate a New York statute which requires that all prescriptions for Schedule II drugs, Public Health Law (hereinafter P.H.L.) § 3306 (Schedule II) be prescribed and dispensed only on an official New York State prescription (the "triplicate" prescription), with one copy thereof to be filed with appellant State Commissioner and the Bureau of Controlled Substance, Licensing and Evaluation (BCSLE) in the New York Department of Health. The complaints sought specifically to invalidate P.H.L. §§ 3331(6), 3332(2)(a) and 3333(4), as to any filing required that allowed the appellant to receive a copy of the prescription that disclosed patient identity.

Thus appellees Richard Roe (a fictitious name) *et al.* commenced the action in the United States District Court for the Southern District of New York against the Health Commissioner challenging the requirement for the use of official state prescription forms. The action was filed on March 29, 1973. Appellees George Patient (also a fictitious name) *et al.* commenced a similar action filed April 3, 1973.*

Roe moved for the convening of a three-judge court and for a preliminary injunction. A temporary stay of administrative implementation of the law, in part, was granted. On the return date Patient was allowed to intervene, but the complaint was dismissed as raising no substantial constitutional issue. (357 F. Supp. 1217). The stay of full implementation was dissolved.

Roe and Patient appealed to the Court of Appeals for the Second Circuit. The stay of implementation, in part, was reinstated pending the appeal. The Court of Appeals reversed the dismissal of the complaint and remanded the

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* The Patient plaintiffs intervened; 357 F. Supp. at 1219, n. 5.

action to the district court for the convening of a three-judge court. The stay, or temporary restraining order, as modified, was continued pending the hearing before the District Court (480 F. 2d 102).

On remand, the statutory district court denied both Roe and Patients' motions for a preliminary injunction and the State's motions to dismiss.* (364 F. Supp. 536).

The State filed an answer and extensive discovery ensued. A trial was held on December 2, 1974. Evidence was also received by way of (1) stipulated facts, (2) depositions taken on December 4 and 6, 1974 and (3) exhibits. The district court filed its unanimous opinion on August 13, 1975 (J.S. la). The opinion held "that so much of the New York [Public] Health Law as requires reporting to state authorities in Albany the names and addresses of patients who receive Schedule II drugs as medication by duly licensed physicians is an unconstitutional interference with plaintiffs' rights of privacy guaranteed under the Fourteenth Amendment." (J.S. 13a).

On October 9, 1975, the district court signed an order which contained a stay suggested by the Roe attorneys. The order (1) declared unconstitutional Public Health Law (N.Y. §§ 3331[6], 3332[2][a] and 3333[4]) as they require disclosure of patient identity; (2) enjoined defendant from enforcing the above provisions and accepting such prescriptions or any other document disclosing patient identity for filing and applied this to any other agency of the State (although appellant has no control over them and none were parties); (3) required the State agency to destroy all records within 60 days; and (4) file an affidavit to that effect.

The district court stayed (3) and (4) pending the State's

* The filing statute did not go into full force and effect until the Court of Appeals vacated preliminary injunctions in two similar actions on September 11, 1973, *New York State Physicians Union* v. *Ingraham* (W.D.N.Y. Civil 1973-248, Civil 1973-281). We are aware of no further proceedings therein.

filing an appeal. However, the State Commissioner was required to place all computer tapes and forms in a sealed vault and he could no longer add names to or make any record from the tapes of patient names. As a consequence patient identity from prescriptions is no longer thereby available to the State.

Facts

The plaintiffs-appellees in both actions are anonymous patients and named doctors and doctor's organizations.* The suits were started on the eve of the effective date of Article 33 of the Public Health Law. The challenged portions of the statute required that on or after April 1, 1973, a practitioner (physicians and others) would have to use an official New York state prescription for prescribing Schedule II drugs, a limited list of narcotic and like substances. Pharmacists could only sell such drugs on the official prescriptions, with exception for emergencies (P.H.L. § 3334).

The official prescription is dispensed in triplicate and only on special order to practitioners. It is required to have certain specified information (P.H.L. § 3332) including patient's name, address and age (§ 3332[2][a]). After the drug is dispensed the pharmacist must file a copy with the Department of Health (3333[4]), or if the practitioner self-dispenses, he must file a copy in similar manner (3331[6]).

The purpose of the filing requirement is found in the legislative history. As stated in the Interim Report of the Temporary State Commission to Evaluate the Drug Laws

* These doctor's organizations are not the usual state or county medical societies. The state medical society declined to get involved or support the Roe action (166a). As a consequence the (rather modest) Empire State Physicians Guild, Inc., allowed a drug company Ciba-Geigy (the makers of Ritalin, a widely abused Schedule II drug) to provide the financial backing for the attack on the statute (167a).

(N.Y.S. Legislative Documents [T.S.C.] [1972] No. 10) at p. 21 (and a part of the "Legislative History"):

> "Once the department has received the copies, it will be able to compile data which will uncover irregularities such as forgeries, fraudulent obtaining of schedule II substances, and thefts of prescription blanks and their misuse by unauthorized persons. The information received by the department will show if a patient has obtained prescriptions by going from doctor to doctor, or if stolen prescriptions are being used. This procedure will also indicate where there has been an over-prescribing or over-dispensing of schedule II drugs. There is a 30-day maximum on the amount of any controlled substances which may be dispensed. Prescriptions for schedule II substances may not be refilled (§ 3339)."

There was no pretense or expectation that multiple prescription and monitoring would solve all problems of drug abuse. Thus at p. 22 of the Interim Report:

> "The Commission has no illusion that the multiple prescription requirement and monitoring of the prescriptions by the department will affect the far more significant problem of street abuse, particularly of the contraband drugs. We do believe, however, that it will be a significant step in reversing the growing trend of diversion and of 'legitimate' abuse of dangerous drugs."

See also the statement of then Governor Rockefeller in approving P.H.L. Art. 33 (McKinney's 1972 Session Laws of New York, Vol. 2, p. 3407):

> "These bills should help reduce the diversion of potentially dangerous drugs from legal medical and research uses into illegal channels. The bills represent a culmination of the efforts of the Temporary

> State Commission to Evaluate the Drug Laws, under the Chairmanship of Assemblyman Chester R. Hardt, to modernize and tighten New York's regulatory controls over the manufacture, distribution and prescription of dangerous drugs throughout the State.
>
> While the bills make an important contribution to stemming the illegal distribution of dangerous drugs, they are admittedly no panacea for curing the drug epidemic destroying the lives of so many of our young people today.
>
> In New York State we have invested over $750 million to fight drug abuse, to treat addicts, to research and apply every promising approach to drug control. But addiction goes on, deaths from overdoses mount, and crimes costing the American people $5 billion a year are committed by addicts to support their habit.
>
> The diversion of legally manufactured drugs to illegal purposes is a contributor to the total drug problem. These measures, designed to stem that insidious diversion, must form part of a total, national response to the drug threat.
>
> The bills are approved."

The expectation was that upon filing the data (including patient identity) from the prescription it would be encoded by means of modern data processing techniques (computers). See Second Interim Report of the T.S.C. April 5, 1971 (also part of the "Legislative History") which reviewed the possible uses of triplicate prescriptions. Also cited were in the operation of similar systems for varying periods in California, Idaho and Illinois.* Noted was their experience and the conviction that "such a program in New York will result in a marked decrease in the abuse of

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* California Health & Safety Code §§ 11158, 11160, 11167; Idaho Code, §§ 37-2722, 37-2730, Ill. S.H. Ann. Ch. 56½, §§ 1308, 1311, 1312(a).

legitimately prescribed drugs'' (p. 21). In other words, triplicate prescriptions and filing can have a prophylactic effect in this area.

As noted in the opinion of the Court (J.S. 2a), the Schedule II drugs, while of some accepted or restricted medical use, also have a high potential for abuse. The monitoring of these drugs by the use of triplicate prescriptions seeks to prevent these drugs from being diverted to illegal uses.

The appellee patients, objecting to the filing of their names on the filed prescriptions, contended the statute was an invasion of their constitutional right of privacy (11a, 17a). The doctors contended that the filing interfered with their constitutional right to practice their profession and prescribe medication or drugs as they saw fit. As such, it was claimed the law infringed on the confidentiality of the doctor-patient relationship.

Basically the appellees speculated that the data collected would be misused, *i.e.*, that they would be labelled ''drug addicts'', that the data would not be confidential, and the like. The actions were begun on or before the complete effective date of the filing requirement, as complete filing and computerization of the prescriptions was delayed until September, 1973 due to various court orders. Thus the above speculation was indeed a complete supposition.

The testimony of the appellees' witnesses is summarized at J.S. 5-6a. The actual operation of the triplicate is only described in the opinion (J.S. 11a) to include the use of patient identity in the printing out lists of patients obtaining more than a 30-day supply of Schedule II drugs or going from doctor-to-doctor to obtain Schedule II drugs.* Actually other uses were testified to (specific inquiries from the field) (423a). Even as to that specific purpose, the cited

* No plaintiff patient testified he would be on the print-out, nor did any doctor testify he would be on the print-out.

single instance (11a) has been joined in the months following trial by dozens of suspect situations revealed by increased scrutiny of print-outs. Obviously this could not be reflected in the record.*

Based on this supposed lack of *results*, the Court below concluded that the State did not *need* patient identity on the filed prescriptions and enjoined the filing or processing of prescription forms containing patient identity.** The order signed permanently prevented any use of patient identity to better enforce Article 33 of the P.H.L. A limited stay allowed the appellant to keep previously processed prescriptions but not make any use of them.

Summary of Argument

(1) The sections of the Public Health Law of New York which require filing with the state official of a prescription copy including patient identity are an exercise of the police power over distribution of dangerous drugs. They do not attempt to control or regulate the individual or his medical treatment. Filing is carefully designed to prevent abuse by diversion of the specified narcotic and amphetamine type drugs from legitimate medical use. Thus the regulation requiring doctors and phramacists to file the Schedule II prescription copy does not infringe on any right of privacy as it has developed in our jurisprudence. This right revolves around an individual's choice, not a relationship with a professional.

* In the September 1975 print-out, the last before the judgment appealed from brought use of the filed prescriptions to an effective halt, 45 reports were made (in one month). These involved patients using the same name to obtain controlled drugs (Schedule II) from multiple sources (doctor-to-doctor). Included also were prescribing over a 30-day supply of a drug and use of forged or stolen prescriptions.

** The opinion held it was ''unnecessary'' to evaluate confidentiality requirements (J.S. 13a).

With the filing of prescriptions there is no personal right involved which this Court has deemed fundamental or implicit in the Constitution. Rather the statute can only be said to affect total anonymity. Yet the latter never exists, having been lost at birth, and at many stages of life it is necessary to reveal one's identity to public officials. Given the State's undoubted interest in the regulation and control of drugs of all kinds, the State has the power to supervise prescription of dangerous drugs.

The physician-patient relationship is not a relationship invoking a fundamental right of privacy as we know it. Cases such as *Roe* v. *Wade,* 410 U.S. 113, and *Doe* v. *Bolton,* 410 U.S. 179, find a right of privacy and protect the woman's right to choose an abortion. They do not protect the doctor-patient relationship. While this right may be asserted in a medical context, the doctor's presence is not what makes a fundamental right.

There are important reasons not to find a fundamental right of privacy in the doctor-patient relationship. Basically it would severely limit the ability of states to mold the doctor-patient testimonial privilege to fit the needs of the public, mandate its creation and put in jeopardy the common reporting statutes whereby doctors report certain conditions to public officials.

(2) It was improper to apply a fundamental interest test to the statutes involved. The statutes need only be rational and serve the State's legitimate interest. The "need" for the statutes cannot be based on the court below's analysis of the results. This is a matter for the legislature, something within the judgment of it, not the courts.

For the courts to test constitutionality as was done below, would be a revival of substantive due process (*Lochner* v. *New York,* 198 U.S. 45) in a manner which gives courts *carte blanche* to strike down laws which seem to the courts unwise or unproductive.

Clearly, only a rational basis is needed for a law regulating the sale of drugs, an area traditionally and firmly within the State's police power. But even if the compelling interest test is applied, the State's interest in the abuse of the prescriptiton of and the use of the dangerous drugs is so compelling as to fully support the provisions of the statute.

(3) Filing patient's names with the prescription serves a sufficient purpose. It is clear filing (and computerization) can disclose multiple sources of prescriptions (doctor-shopping), excessive prescriptions, and forgeries. The necessary follow-ups by investigators is assisted by patient identity. Not having such identity seriously interferes with the efficient operation of the program. The State, given its limited resources, cannot accomplish what it seeks if the filed prescriptions lack patient identity.

The possible uses of the prescriptions are varied and do not depend on whether at the time of trial they were not yet being so used.

(4) By providing for confidentiality of patient identity, P.H.L. § 3371 prevents any invasion of privacy. The statute, on its face, does so and such confidentiality provisions have been recognized as defeating a claim that privacy is invaded by a filing or medical review program.

The program herein will only use data and patient identity for purposes consistent with the program. Filing of prescriptions in no way stigmatizes the patient.

(5) The patients and doctors presented a claim based on fear and conjectures which had no basis in the filing law as written or administered. The court below gave standing or found a real case on a string of conjectures or hypotheses. The issues in this case was not privacy, but whether erroneous "feelings" can lead to finding unconstitutional a legitimate exercise of the police power. This is simply "ingeneous pleading", not stating a real case or controversy.

I. The challenged statutes are within the State's unquestioned authority to regulate drug abuse.

Article 33 is concerned with the pervasive problem of drug abuse. The statutes here challenged are directed solely at the control of substances which are extremely dangerous, potentially resulting in "severe psychological or physical dependence", *Roe* v. *Ingraham*, 480 F. 2d 102 (2d Cir. 1973). The appellees contest neither the tremendous scope of New York's drug problem nor the obviously legitimate necessity of complete state regulation of dangerous drugs. Recognizing the State's legitimate interest in regulating dangerous drugs, *Roe* v. *Ingraham*, 403 F. Supp. 931, the judgment appealed from nevertheless precludes any effective regulation.

The challenged provisions are carefully designed to further legitimate and important state interests in controlling the dangerous drugs and preventing their diversion into the illegal market. The State is also concerned with the growing trend of careless or unnecessary prescription and over-prescription. The statutes are intended to regulate the use of dangerous drugs in the expectation of controlling and deterring drug abuse. The filing requirements of the state statutes are carefully designed to achieve the purposes of the statute. While allowing the physician or practitioner complete freedom to treat his patient as he sees fit, the statute endeavors to control the unfortunate fall-out of current practices.*

There is no question that the state has an almost absolute right to control the sale, prescription, and use of danger-

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* As an example, see *United States* v. *Warren*, 453 F. 2d 738 (2d Cir. 1971), cert. den. 406 U.S. 944. The Court of Appeals for the Second Circuit in affirming the District Court, held in *Warren* "that the offense, involving serious danger to the physical and mental health of many hundreds of unsuspecting people, was a particularly callous example of the increasingly severe problem of drug abuse", *id.* at 744.

ous drugs. In the now vintage ruling in *Whipple* v. *Martinson*, 256 U.S. 41, 45, this Court said:

> "There can be no question of the authority of the State in the exercise of its police power to regulate the administration, sale, prescription and use of dangerous and habit-forming drugs, such as are named in the statute. The right to exercise this power is so manifest in the interest of public health and welfare, that it is unnecessary to enter upon a discussion of it beyond saying that it is too firmly established to be sucessfully called in question."

This was repeated with approval in *Robinson* v. *California*, 370 U.S. 660, 664. Also "[s]uch regulation, it can be assumed, could take a variety of forms." The wisdom of any particular choice within the wide spectrum of possibilities is not for the courts to decide.

State courts have forcefully reiterated government's authority to regulate dangerous drugs under the police power. In New York, "[t]he Legislature has undoubted power to regulate the manufacture or sale of drugs, including proprietary medicines, in respects which are related to public health." *Loblaw, Inc.* v. *N.Y.S. Bd. of Pharmacy*, 11 N Y 2d 102, 111, 226 N.Y.S. 2d 681, 687 (1962). And *Brodsky* v. *Cal. State Bd. of Pharmacy*, 173 Cal. App. 2d 680, 344 P. 2d 68, 74 (1959), asserted, "[t]he business of compounding prescription and selling drugs is intimately connected with and has a vital relationship to the health, safety and welfare of the public. Public safety must be regarded as superior to private rights." See also *State* v. *Braun*, 209 Kan. 181, 495 P. 2d 1000, 1004-1005 (1972), *cert. den.* 409 U.S. 991.

The challenged statutes are solely designed to protect the public through regulating the prescription of dangerous drugs. The requirement of filing an official prescription with the name and address of the patient using the dangerous drug is within the reasonable exercise of the State's

police power. The "requirements are an essential means of gathering the data necessary" to achieve the statutory purpose (*Buckley* v. *Valeo*, —— U.S. ——, 46 L.Ed.2d 659, 711, 715 [1976]), and should have been upheld.

II. There has been no infringement on any right of privacy.

The opinion below is premised on the erroneous assumption that merely requiring the filing of an individual's name and address is a violation of the right to privacy and that the physician-patient relationship is a constitutionally fundamental relationship that requires meeting a compelling state interest standard. An examination of the developing right of privacy indicates that the lower court's approach is a radical departure from the limitations set by this Court.

The challenged statute in no way prohibits or regulates human behavior such as marital privacy, *Griswold* v. *Connecticut*, 381 U.S. 479, or the use of contraceptive devices; *Eisenstadt* v. *Baird*, 405 U.S. 438 (1972). Unlike *Griswold* and *Eisenstadt*, the New York statutes do not absolutely prohibit, much less interfere with an individual's determination as regards treatment. It merely regulates the distribution of certain dangerous drugs.

There is no added burden or interference placed upon the patient to secure the prescribed drug. As before, the decision whether or not to prescribe the drug is left entirely to the doctor. Although appellees may claim a psychological effect of the filing requirement on some patients who are not objectively and fully informed or who are wrongly counselled, certainly this potential effect, besides not being established upon the record, would have to be hypothetical and minimal.*

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* It has been held that such "fear" does not even support a cause of action. *Laird* v. *Tatum*, 408 U.S. 1, 13-14 (1972).

Reliance upon the right of privacy referred to in *Roe* v. *Wade*, 410 U.S. 113 and *Doe* v. *Bolton*, 410 U.S. 179, is misplaced. The Texas statute in *Roe* absolutely prohibited abortion except as necessary to save the mother's life. The Georgia statute in *Doe* directly prohibited abortion in most circumstances and imposed certain procedure conditions *before* the abortion which had the effect of prohibiting abortions in situations where otherwise allowed. To compare the serious impact of the facts in those cases with the filing requirement here and its hypothetical effect is like comparing apples to oranges. There is no relationship.

In *Roe*, this Court refrained from giving "privacy" the status of a fundamental right. In citing a series of decisions, the Court noted that "only personal rights that can be deemed 'fundamental' or 'implicit in the concept of ordered liberty,' *Palko* v. *Connecticut*, 302 U.S. 319, 325 (1937), are included in this guarantee of personal privacy", *Roe* v. *Wade*, *supra*, at 152. The personal right this Court identified in *Roe* and *Doe* is the woman's right to terminate pregnancy. The Court explicitly rejected the theory that a woman had an absolute privacy right to terminate her pregnancy at will, *Roe*, *supra*, at 153. Instead the Court found that "a state may properly assert important interests in safeguarding health, in maintaining medical standards, and in protecting potential life," *Roe* at 154.

There is no support in *Roe* v. *Wade*, *supra* or *Doe* v. *Bolton*, *supra*, as cited by the Court below (J.S. 18a), for the expansive concept that there is a fundamental right to privacy in the simple doctor-patient relation, regardless of the context or setting. Nothing in either *Roe* or *Doe* even suggests that the doctor-patient relationship is fundamental. Although the decisions state that the decision of a woman to have an abortion should be made in consultation with a doctor (*Doe*, *id.* at 191-192, *Roe*, *id.* at 163), it is the

woman's right to make *the decision to have an abortion* which is the fundamental privacy right protected by *Roe, id.* at 153. It was not the doctor-patient relationship which made the decision to have an abortion a part of the fundamental privacy right. In reality, only the actual interference with *the decision to have or perform the abortion* as in *Doe* (committee review of abortions) limited the right to an abortion.

On the other hand no case can claim a fundamental right to receive dangeorus drugs. The court below concedes this state interest (J.S. 11a).

To assert that *Paris Adult Theatre I* v. *Slaton,* 413 U.S. 49, 66, n. 13 (1973) "reaffirmed the holding in *Roe* and *Doe* that privacy embraced the doctor-patient relationship" as in the decision below (J.S. 9a) is unsound. In *Slaton,* this Court noted (fn. 13):

> ". . . the constitutionally protected privacy of family, marriage, motherhood, procreation, and child rearing is not just concerned with a particular place, but with a protected intimate relationship. Such protected privacy extends to the doctor's office, the hospital, the hotel room, or as otherwise required to safeguard the right to intimacy involved . . ."

While the court below relied on this language, it is clear that this Court distinguished between constitutionally protected relationships (of privacy) and the possible places in which the right to privacy in *those relationships* are asserted. Only if such a relationship already existed, would the "doctor's office" get involved. The *Slaton* decision (fn. 13) did not say that the doctor-patient relationship was constitutionally protected, nor did it purport to grant constitutional protection to any of the mentioned places.

The private nature of a transaction (and sale of drugs, even via prescriptions, is still a commercial transaction)

does not invoke a right of privacy. See *United States* v. *12 200-ft. Reels of Film,* 413 U.S. 123, 127-128 (1973), involving importation of obscene materials for private use. As said therein by way of analogy (128):

> "To allow such a claim would be not unlike compelling the Government to permit importation of prohibited or controlled drugs for private consumption as long as such drugs are not for public sale or distribution".

And further the Court noted, at 129, once obscene material is in the country, it is extremely difficult to control the use to which it is put.

There are several important policy reasons against holding that the doctor-patient relationship is a fundamental interest. (1) The holding below might mandate creation of a doctor-patient testimonial privilege in states that do not have one; (2) the holding below would limit state variations on the privilege; and (3) the holding below would put in jeopardy numerous salutary state statutes requiring doctors to report certain types of case to state authorities (child abuse, venereal disease, bullet wounds, drug addict). See generally, 50 N.Y.U. Law Rev. 1149, 1159-1160, *The Right to Privacy.**

Finally, to the extent that the challenged statutes concern the physician patient-relationship, it is self-evident that there is no substantial encroachment on that relationship. No restraint is placed upon the physician's bona fide prescription of schedule II drugs. The doctor's medical decision as to how to treat his patient best is unhampered. Similarly, there is absolutely no restriction on a patient's

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* This Note criticizes the use of a compelling or fundamental interest test herein and suggests something called "middle level scrutiny" *ibid.* at 1161. It is submitted that there is no such level. Either the interest is "fundamental" or not. If not, a *rational* basis is the test. *infra,* III.

medically supervised use of a schedule II drug. Even before the statute was enacted, the identity of the patient was subject to disclosure. Furthermore, the confidentiality provisions of the statute prohibit unauthorized disclosure (§ 3371) thereby effectively removing any rational fear of stigmatization. The only effect on the physician-patient relationship is to have the doctor use an official prescription blank.

Here there is no personal right which can be deemed fundamental or constitutionally implicit. The only asserted encroachment by the challenged statutes is to the dubious right of total anonymity. (Thus at J.S. 12a the District Court held that the dispersal of records as a value to be protected.) To hold that such anonymity is within the scope of the right of privacy, much less a fundamental personal right, is a radical departure from commonly accepted standards. Anonymity is lost at birth with the filing of birth certificates. The filing of death certificates deny anonymity even in death. To exercise the right to work requires giving up anonymity by registering with the Social Security Administration. To receive income, earned or unearned, involves the payment of taxes, again destroying anonymity. Even the fundamental right of voting requires giving up anonymity by registering or contributing *Buckley* v. *Valeo,* —— U.S. ——, 46 L.Ed. 2d 659, *supra.* Anonymity is also lost because of fingerprinting requirements in certain jobs. *Thom* v. *New York Stock Exchange,* 306 F. Supp. 1002 (S.D.N.Y. 1969), affirmed 425 F. 2d 1074 (2d Cir.), cert. den. 398 U.S. 905.

To contend that supposed right of anonymity is strengthened by the context of taking drugs to insure medical health is a frivolous and bootstrap argument. The absolute power of the State to regulate the use prescription and sale of dangerous drugs has already been shown, *Whipple* v. *Martinson, supra,* 256 U.S. 41, 45. No violation of constitutional rights is involved in the inspection

of a physician's narcotic or drug records. *Anderson* v. *Reynolds,* 342 F. Supp. 101, 111 (D. Utah, 1972). The license to practice medicine is not a license to distribute drugs. *Brown* v. *United States,* 250 F. 2d 745 (5th Cir.), *cert. den.* 356 U.S. 938. The State may supervise drug transactions between physicians and patients, particularly as a control against drug abuse and diversion. The argument of appellees is more frivolous since the State has not even requested the purpose for which the drug is being prescribed. Furthermore, the statute's confidentiality provisions assure the individual's privacy (preservation of personal autonomy) by safeguarding the use of patient identity (V, *infra*).

Other cases where this Court has explored the scope of right of privacy emphasize that the case at bar is beyond the parameters of the right of privacy. For instance, in *Kelley* v. *Johnson,* —— U.S. ——, 44 L.W. 4469 (April 5, 1976), this Court recently held that the right of a policeman to wear his hair a certain length is not within any right of privacy. In this area of public safety, *i.e.,* the State's police power, the test is not whether the State can "establish" a "genuine public need" (4472) for a specific regulation as the Second Circuit held (508 F. 2d 836, see *Dwen* v. *Barry,* 483 F. 2d 1126, 1130-1131). Rather it is a rational connection between the regulation and the promotion of safety. Further the courts are not in a position to weigh policy considerations for or against a regulation. A traditional rational basis test, *Williamson* v. *Lee Optical,* 348 U.S. 483, 487-488 (1955), was applied in *Kelley* (*infra,* III).

Even in a clear patient-doctor case, this Court affirmed the dismissal of the complaint in *Association of American Physicians and Surgeons* v. *Weinberger,* 395 F. Supp. 125 (N.D. Ill. 1975), affd. *sub nom. Association of A. P & S* v. *Mathews,* —— U.S. ——, 46 L. Ed 2d 299, 96 S. Ct. 388. The case clearly indicates that official review of a physi-

cian's practice does not interfere with any constitutional right to practice medicine or invade the privacy of patients. The *Weinberger* case, 395 F. Supp., at 135, cites the confidentiality provision, 42 U.S.C. § 1320a-15, to negate any invasion of privacy.

This Court has also had occasion to explore privacy within the context of disclosing confidential reports and records. Thus in *Fisher* v. *United States,* —— U.S. ——, 44 L.W. 4514 (April 21, 1975), this Court held that tax records of a client were not immune from productions when in the possession of his attorney. The Court examined the purpose of the attorney-client relationship, 4518, and found it did not encompass papers in the hands of an attorney. The privilege is to encourage a client to make full disclosure to his attorney. By analogy the information on the prescription (drug, dosage, name, address), which is available to appellant in any event, is not the type of disclosure necessary for the patient to obtain medical treatment—the purpose of the medical privilege. By filing the prescription the appellant learns nothing about the underlying illness or malady.

And in a sequel to *California Bankers Assn.* v. *Schultz,* 416 U.S. 21, this Court held in *United States* v. *Miller,* —— U.S. ——, 44 L.W. 4528 (April 21, 1976), that bank records kept by virtue of the Bank Secrecy Act record-keeping requirements are not protected by some right of privacy. The records are not the "private papers" of depositor. By way of analogy, the prescriptions herein are not the "private papers" of appellees. They are business records permitting the sale of controlled drugs. While the records in *Miller* were subpoenaed, the lack of a subpoena for the appellant to have access to the prescription is no objection to the filing process. *United States* v. *Biswell,* 406 U.S. 311 (1972) upheld access by government agents to gun records, where the business (guns) is prevasively regulated the persons engaged in same does so with knowledge that the records will be subject to effective inspection (316). There is no doubt prescribing and sale of dangerous or controlled drugs is closely regulated and licensed.

Pertinent also is this Court's ruling in a case involving a similar federal drug control statute requiring official prescriptions open to official inspection where this Court found no constitutional problem. *Minor* v. *United States,* 396 U.S. 87. There the same type of official prescription in triplicate, 26 U.S.C. § 4742(a), was described, *id.* at 90. Failure to use this form was upheld against a claim of self-incrimination. If this type of procedure is unobjectionable in face of a clearly defined constitutional right, then it stands against some undefined right of privacy. (It should be noted that the above federal law has been repealed and replaced by the comprehensive Drug Abuse Law in 21 U.S.C. § 801 *et seq.*)

From the foregoing, it is evident that the filing requirement of P.H.L. §§ 3331(6), 3332(2)(a) and 3333(4) does not violate the right of privacy as that doctrine has been as yet developed by this Court.

III. The Court below improperly applied a fundamental interest test. It should have applied a rational basis analysis. In any event the legislation meets the test imposed by the Court.

As we have demonstrated the privacy right allegedly affected by the challenged statutes do not involve a fundamental right. Similarly, fundamental status cannot be achieved in the guise of the doctor-patient relationship. Therefore, the challenged statutes, like any exercise of the state's police power must be measured by a standard of reasonableness. Where the public safety is involved, the State need not use only such means that satisfy some court's judgment as to proper breadth of regulation as when the First Amendment is involved, *Erznoznik* v. *City*

of Jacksonville, —— U.S. ——, 45 L. Ed. 2d 125 (1975), and cases cited below (J.S. 11a). Obviously the statute in question does not involve infringement of the First Amendment and appellees do not so claim.

Thus the discussion of "needlessly broad sweep" (J.S. 11a) is off the mark. Given the concession by the district court that the state effort to control drug abuse was legitimate (J.S. 11a), and the proposition, and as advanced in II, *supra,* that we are not dealing with a constitutionally protected right (to privacy, First Amendment, or intimate familial or sexual relation), the test to be applied is whether the statute with the filing and computerization is rationally connected to the statute's purpose. While the rational basis test, *McGowan* v. *Maryland,* 366 U.S. 420, *United States* v. *Carolene Products Co.,* 304 U.S. 144, 152, is normally applied to a claim of denial of equal protection, it can be applied to a claim of denial of due process (or right of privacy), as in *Kelley* v. *Johnson, supra.* Even the District Court herein had to concede at a minimum that filing of the prescription including patient identity had merit and was essential to ferreting out instances of over-prescription and multiple sources (doctor-to-doctor) (J.S. 11a).

There is simply no authority for the proposition, as advanced and used by the District Court (J.S. 11a), that the administrative yield or results of a program would be the test of constitutionality. If it were, the constitutionality of a filing requirement would be dependent on the level of administrative efficiency of the State's administration of the program. Thus the identical prescription filing statute would be constitutional in Idaho, for example, if the yield satisfied some federal judge there that the effort was worth it. Based on the District Court's pragmatic evaluation of a legitimate state effort, the program would be approved or invalidated as the case may be. Clearly if the effort herein was not justified by the results, this is a matter for the legislature, not the Courts.

Obviously the legislature, after some study (J.S. 2a) determined there was a need for use of triplicate prescriptions for the dispensing of dangerous drugs together with filing with the State agency charged with the enforcement of the law. Computerization of filed prescriptions was contemplated as assisting in the efficient enforcement of the law.* Whether filing will ultimately achieve all the aims envisioned by the legislature is not the issue. Whether these hopes are achieved in the end does not affect the law's constitutionality. As said in *James* v. *Strange,* 407 U.S. 128; 133-134:

> "We turn therefore to the Kansas statute, aware that our reviewing function is a limited one. We do not inquire whether this statute is wise or desirable, or 'whether it is based on assumptions scientifically substantiated.' *Roth* v. *United States,* 354 U. S. 476, 501 (1957) (separate opinion of Harlan, J.). Misguided laws may nonetheless be constitutional. It has been noted both in the briefs and at argument that only $17,000 has been recovered under the statute in its almost two years of operation, and that this amount is negligible compared to the total expended. Our task, however, is not to weigh this statute's effectiveness but its constitutionality. Whether the returns under the statute justify the expense, time, and efforts of state officials is for the ongoing supervision of the legislative branch."

And in *Mourning* v. *Family Publication Service, Inc.,* 411 U.S. 356, 378:

> "It is not a function of the courts to speculate as to whether the statute is unwise or whether the evils

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* Efficiency in the achievement of a legitimate State purpose is not unconstitutional. *Rosario* v. *Rockefeller,* 410 U.S. 752, 762, ftn. 10. This so, even where fundamental rights such as voting are involved.

sought to be remedied could better have been regulated in some other manner."

' The question of the power of the legislature is not to be confused with the entire range of legislative considerations when dealing with a matter of policy. The three-judge court herein could not indulge in a legislative judgment. Yet it did and this was erroneous. *Brotherhood of Locomotive Firemen & Enginemen* v. *Chicago & R.I. & P. Rd. Co.*, 393 U.S. 129, 136; see also *Cohen* v. *Beneficial Finance Corp.*, 337 U.S. 541, 548-549.

In actuality, the district court has resuscitated erroneously the theory of substantive due process. See 48 N.Y.U. Law Rev. 670, 773 (1973) *Note: On Privacy.* The instant decision does not protect any identifiable personal liberty of appellees but rather interferes with a firmly established state right which was recognized some fifty years ago in *Whipple* v. *Martinson, supra.*

In spite of the district court's conclusion that the State is interfering with the practice of medicine, the statutes at issue are simply regulating the process of prescribing a limited area of drugs, Schedule II dangerous drugs. *Roe* v. *Ingraham, supra,* 357 F. Supp., at 1221. Obviously the statutes do not prevent the patient from disclosing his problem to the doctor. In contrast to *Roe* and *Doe,* where the woman's choice to have an abortion was protected, the decision to prescribe a certain drug is solely the doctor's. The patient does not choose the specific drug to treat his ailment.

Given the situation that New York has a right to regulate the business of dispensing drugs, the procedural process should only be subject to a test of "reasonableness".* *McGinnis* v. *Royster,* 410 U.S. 263, 270. The de-

* New York recognized, by providing for confidentiality of patient identity, P.H.L. § 3371 that it was dealing with a sensitive area.

termination that filing with patient identity would serve a useful function in controlling drug abuse and diversion require only some rational basis. The regulation further some legitimate, articulated State purpose, *McGinnis,* at 270; *Roe* v. *Ingraham,* 357 F. Supp. at 1220-1221. And contrary to the decision below this Court in *McGinnis, id.* at 271, would "pass no judgment on the success or merits of the State's efforts . . .".

The only justification for application of strict judicial scrutiny is when some fundamental right is being infringed. *Doe* v. *Bolton, supra* (abortion); *Harman* v. *Forssenius,* 380 U.S. 528 (1965) (voting).

If the appellees argue for something called "middle-level scrutiny", see 50 N.Y.U. Law Rev., *supra* at 1161, the answer is simple. It does not exist. Any argument for it does not find support in decisions of this Court. Whether, the classification, *in fact,* advanced a legitimate State end, *On Privacy,* 48 N.Y.U. Law Rev., *supra* at 703, is simply another statement of the rational basis analysis. *Population Services Int'l.* v. *Wilson,* 398 F. Supp. 321 (S.D.N.Y. 1975), app. pdg. 44 U.S.L.W. 3162 (Sept. 20, 1975), cited by 50 N.Y.U. Law Rev. *supra,* as middle level, depended on *carefully scrutinizing* the statutory provision. This was treating the right (to contraceptives) as fundamental. It cited *Boraas* v. *Village of Belle Terre,* 476 F. 2d 806 (2d Cir. 1973).* However *Boraas* was not reversed on other grounds, 416 U.S. 1 (1974). Specifically this Court said at 416 U.S. 8, that *Boraas* did not involve "fundamental" right, or privacy and thus only a "rational relationship to a [permissible] state objective" citing *Reed* v. *Reed,* 404 U.S. 71 (1971), was the proper test. Clearly this Court has not found a third test. The filing of prescriptions will,

* It is interesting that the initial decision herein, 357 F. Supp. 1217, 1221 also cited *Borass* and found the filing statute in issue met the test.

in fact, advance the State's objective if it is given a chance to operate. Its very existence deters drug abuse via the prescription route and does not depend on the efficiency of appellant's computer.

IV. The requirement of filing patient names on prescriptions is a rational exercise of New York's police powers and serves a sufficient purpose.

We have already in I, *supra,* explored the power of a state over the use and distribution of drugs, and especially dangerous ones. See *Whipple* v. *Martinson, supra.* A requirement that a practitioner report, on a regular basis, the names of "drug-dependent" persons invades no right and privacy and is within the State's power. *Felber* v. *Foote,* 321 F. Supp. 85 (D. Conn. three-judge court 1970). *Felber,* at 88, relied on *Katz* v. *United States,* 389 U.S. 347, 350-351 (1967) which stated:

> "But the protection of a person's *general* right to privacy—his right to be let alone by other people—is like the protection of his property and of his very life, left largely to the law of the individual States." (ftn. omitted).

While the appellees will undoubtedly talk about the State "conceding" (Appellee Roe's Motion to Affirm, p. 25) and the Court's findings, the requirement of filing need not be considered on a limited or constricted basis if it rationally advances New York's purpose to control and, hopefully, eliminate or reduce the abuse of dangerous but medically useful prescription drugs.*

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* Often drugs, such as in Schedule II, have been subject to strict prohibitions with even scientific experimentation limited. See, 73 Col. L. Rev. 372, Book Review of "Dealing with Drug Abuse" (Feb. 1973).

By focusing simply on the one regular computer print-out that would contain patient identity, the district court erroneously concluded that the filing of the triplicate prescriptions was not necessary or added nothing to the State's efforts. This is an utter fallacy which on even cursory analysis does not stand up. Even the Court's "Findings of Fact" stated the use as "thus far" (J.S. 5a). It did not preclude other uses.

In talking of one or two instances (J.S. 5a, 11a) of doctor shopping or overprescription referred by the computer, the district court necessarily had to hold that computerization was the only reason for filing. While probably the major rationale, the courts cannot pick and choose what aims of legislation are primary and which subordinate. *McGinnis* v. *Royster,* 410 U.S., at 276, *supra.* Even if computerization of the filed prescriptions was never attempted and no print-out ever made,* the prophylactic effect of filing Schedule II prescriptions is rational and obvious. Knowledge of filing would have the rational result of reducing drastically the over-prescription of Schedule II drugs. Bogus patients and unscrupulous doctors would hopefully cease their activities.** Indeed if the district court presented a proper picture of the results from use of computerization, it would be a proper conclusion that the filing system had virtually eliminated the abuse it was directed to.*** As stated in the *T.S.C.,*

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* Actually 24 referral were made by computer analysis using patient identity from April 29, 1974 to February 28, 1975. Some revealed forgeries. Three resulted in criminal action or arrest, one in civil action and as of now 12 are still pending.

** Filing enables the appellant to more quickly uncover and locate bogus and sham prescriptions which are not confidential anyway. *Kaplan* v. *Kaplan,* 31 NY 2d 63, 67, 286 N.E. 2d 260 (1972).

*** Unfortunately, this is not the case. In the September, 1975 print-out there were 45 instances or referrals of over-prescription

(*footnote continued on following page*)

supra, the program reduces abuse of legitimately prescribed drugs.

The district court attempted to buttress its conclusion that the filing requirement was of no use by alluding to in a footnote (J.S. 11a), that (1) the prescriptions will be of no aid in preventing addicts from getting drugs by prescription (2) besides they would not use their own name or the same name and (3) the plaintiffs doctors testified they would spot addicts. The above rationales are totally fallacious. (1) the law, P.H.L. § 3380 prohibits the prescribing, administering or dispensing of "controlled substances" (Schedule II drugs) to addicts or habitual users except for research, §§ 3324 *et seq.* (Title III of Article 33 of P.H.L.) and under specific situations covered in Title V, §§ 3351 *et seq.* (2) The court assumes that addicts will violate another prohibition, P.H.L. § 3397, by obtaining the Schedule II drugs (by fraud and deceit). A law cannot be assumed to be unnecessary because some people may violate it. (3) Maybe the appellee doctors are so "expert" that they can spot addicts who come into their offices. However, the T.S.C. (Interim Report, p. 21) noted that many physicians felt that some "inhibition on over-prescribing was long overdue, and that the medical profession had demonstrated a clear inability to police itself in this regard."* The testimony of the appellees also flies in the face of the well-documented fact that there are doctors who are not interested in using these dangerous drugs properly

(*footnote continued from preceding page*)

and/or multiple sources (doctor-to-doctor shopping). Unfortunately due to the injunction below no follow-up action could be taken. Several of these items included use of stolen and/or forged prescriptions.

* The federal Drug Enforcement Administration (Registrant Facts, Vol. II, #3, September 1975) has asked physicians to make special efforts as to amphetamines to insure that multiple prescription orders are not being obtained by a patient from different physicians.

but simply sell drugs. For instance, see *United States* v. *Warren, supra,* 453 F. 2d 738 (2d Cir.). And some "medical" sources are so well known as to be the subject of newspaper articles (New York Times, Dec. 4, 1972, p. 1, re: Dr. Max Jacobson, and Mar. 25, 1973. "Two Doctors Here Known as Sources of Amphetamines").

The district court attempted to say that the State could ferret out over-prescribing and forgeries without use of patient identity. Concededly, there was no way of simply locating persons using multiple sources without filing. The 24 Bureau of Narcotic Control investigators (J.S. 4a, 5a) cannot go over 100,000 prescriptions without some mechanical assistance.* The decision ignores the illicit prescribing of drugs for over 30-days. Presently there is a print-out with this but without patient names. Thus investigators have to go out physically to pharmacies to obtain the names of patients. The additional step obviously interferes with the State's efforts. Furthermore to conclude that patient identity adds nothing to investigating forgeries and stolen prescriptions is also fallacious. Obviously the computer cannot know a name is a forgery. However, lost, stolen and forged prescriptions are required to be reported. From this the appellant (BCSLE) prepares a regular list of same (like the credit-card companies do) and distributes it to pharmacies. If a person comes in to a pharmacy with one of these prescriptions, the use same may be stopped, or hopefully apprehend the forger. For example, the BNC may be called. Even so, the stolen, etc., prescriptions are often used by one person which can only be detected by use of patient identity (BCSLE had a computer-referral case

* Many of the 45 referrals in September 1975 involved a person obtaining prescription from multiple sources and cashing the prescriptions in several pharmacies, the only place BNC investigators can now obtain the identity of patients.

involving an "E.K." in Long Beach, N.Y. with three different doctors and two pharmacies). Without patient identity the appellant cannot properly investigate these matters. Indeed such information is necessary to verify the correctness of the filed prescription, if it is in question.*

Other uses, although not contemplated by the District Court, or perhaps even appellant, are the use of patient identity in criminal investigations. The statute, P.H.L. § 3371(1)(b) clearly contemplated that on *court order* the patient's identity would serve a useful purpose in criminal investigations. An example is a court order obtained by the Westchester County District Attorney in the investigation of the death of a doctor from morphine intoxication. In seeking the possible source of the morphine, the printouts of the deceased doctor, his wife (also a doctor) and his patients were requested. However without patient identity servicing of such legitimate court orders (P.H.L. § 3371 [1][b]) is impossible.

Finally, the statute contemplated use of prescriptions containing patient identity in professional disciplinary proceedings. P.H.L. § 3371(2). Without patient identity, prompt action against unethical doctors is impeded. The filed prescription may be the only evidence of a doctor's abuse of his patient.

The District Court's contention that patient identity adds nothing is simply an expression of judicial Luddism.**

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* Prescriptions have been written in the name of a professional sports team ("Buffalo Bills") and not the individual patient. Here this is spotted before the prescription is even processed for the computer.

** So called after the band of workmen (1811-16) who tried to prevent the use of labor-saving machinery by breaking it, burning factories, etc. (Webster's New Int. Dictionary 2nd Ed.)

The use of filing allows instant retrieval via computerization but what the district court condemned (J.S. 12a) was paradoxically accepted in the single-judge opinion, as one of the "facts of present day life." (357 F. Supp., at 1222.) No one need be insensitive to the dangers posed by modern computer technology. However where the system has a properly defined purpose with strict provisions to prevent misuse of the data, it is not the function of the courts to destroy the operation based on vague, unarticulated "fears" having no rational support or relation to the law or the appellant's operation.

We do not believe that it was in any way proper to test the constitutionality of filing on the basis of "results". The test in making reports should be "a high degree of usefulness in . . . investigations or proceedings". See *California Bankers Ass'n.* v. *Schultz*, 416 U.S. 21, 26, *supra*. Patient identity at the very least, is highly useful to the Department of Health fulfilling its obligations.

Reporting of certain transactions has such a long-standing history as not really to be in issue. Thus the Internal Revenue Service obtains information on all kinds of payments, 26 U.S.C. § 6031 *et seq.* reports on W-2 forms and interest income statement (Form 1199), 26 U.S.C. § 6049 (1). These, we presume, are computerized to compare with filed income tax returns. In New York, attorneys in the First, Second and Fourth Judicial Departments must file retainer statements and closing statements (including client's names) on contingent fee cases; 22 N.Y.C.R.R. §§ 6037, 691.20, 1022.2, 3. Some challenge was made and rejected, although not on privacy grounds. *Gair* v. *Peck*, 6 N Y 2d 97, 160 N.E.2d 43 (1959), app. dsmd. 361 U.S. 374.

V. Confidentiality is insured by the statute, preventing any possible infringement of any asserted right of privacy.

The opinion of the three-judge court expressed concern that the reporting requirements of the challenged statutes would involve "broadcast to unauthorized sources" (J.S. 10a) and the consequential stigmatization of persons making beneficial medical use of Schedule II drugs (403 F. Supp. 931). This concern is ill-founded because it fails to consider the statutory requirements of confidentiality, the purpose and operation of the filing requirements and attaches an inappropriately sacrosanct status to the doctor-patient relationship. There is no record evidence to support the contention.

A. The statute, on its face, insures confidentiality

The challenged sections of the Public Health Law [§§ 3331(6); 3332(2)(a) and 3333(4)] merely require the filing of the patient's name and address on a special prescription form (29a). This differs from the prior, and presumptively constitutional, law only by the requirement of central filing with the Department (*Roe* v. *Ingraham, supra,* 480 F. 2d at 108). In his opinion for the Court of Appeals, reversing the dismissal of the action and ordering a three-judge court, Judge Friendly emphasized that the ambiguity of New York Public Health Law § 3371 would make it potentially ineffective in guaranteeing the confidentiality intended by the statute. Partially in response to Judge Friendly's opinion, the New York Legislature amended Public Health Law § 3371 to better insure the confidentiality of the records by more specifically identifying the persons who may have access to the records and for what limited purposes. Furthermore, the legislature amended Section 3370 by providing that all records

of the name of any patient received pursuant to the filing sections herein challenged must be destroyed within five years of receipt.

It is fundamental that in reviewing the constitutionality of any statute, all statutory qualifications on the operation of the challenged statute must also be considered. *Kokoska* v. *Belford,* 417 U.S. 642, 650, citing *Brown* v. *Duchesne,* 19 How. (60 U.S.) 183, 194. It may be inferred (from an utter lack of discussion) that the three-judge court failed to consider the effect of Sections 3370 and 3371 in qualifying the challenged sections of Article 33. On its face the statute guarantees the individual's right of privacy by providing strict limitations on divulgence (§ 3371) and exact time limitations (§ 3370) on the use of the information filed under the challenged statutes. Since the filing requirements pertain only to the names and addresses of patients without even mentioning the malady for which the drug is being prescribed, the assertion of intrusion into the individual's privacy is insincere but in any event is at most, *de minimis.* The statutory requirements of confidentiality more than effect any potential risk that any individual's asserted privacy might be violated or that there will be a "broadcast to unauthorized sources" with resulting stigmatization. It is obvious that these are "articulated fears" (*Buckley* v. *Valeo,* 46 L. Ed. 2d, at 715), without substance.

By affirming the three-judge court opinion in *Association of American Physicians & Surgeons* v. *Mathews,* —— U.S. ——, 46 L. Ed. 2d 299, 96 S. Ct. 388, this Court indicated that government regulation to achieve a legitimate State purpose will not be held to violate any individual's right of privacy when these are adequate safeguards of confidentiality. The three-judge court opinion in *Association of American Physicians & Surgeons* v. *Weinberger,* 395 F. Supp. 125, 138, had specifically found that there was no interference with the right of privacy because of the

statutory provisions designed to assure confidentiality. This case involved a challenge to the federal Professional Standards Review Law. The confidentiality provisions of that law, 42 U.S.C. § 1320c-15, are no broader and less detailed than the provisions of P.H.L. §§ 3371 and 3370. Like 42 U.S.C. 1320c-15, the New York statute provides criminal penalties for violation of the confidentiality provisions. Public Health Law § 3396(2) provides that:

> "2. Violation of any provision of this article for which a penalty is specifically provided herein shall be punishable as provided herein. Violation of any provision of this article for which no penalty is provided herein shall be punishable as provided in section twelve-b of article one of this chapter or in the penal law."

Public Health Law § 12-b(2) further provides the following penalties:

> "2. A person who wilfully violates any provision of this chapter; or any regulation lawfully made or established by any public officer or board under authority of this chapter, the punishment for violating which is not otherwise prescribed by this chapter or any other law, is punishable by imprisonment not exceeding one year, or by a fine not exceeding two thousand dollars or by both."

The court in *Weinberger* distinguished the confidentiality provisions of P.H.L. § 3371, based upon the Court of Appeals opinion in the instant case (480 F. 2d 102). Since the Court of Appeals decision in *Roe,* the New York legislature has amended the confidentiality provisions. They now expanded and more specific provisions are distinguishable from those relied on in *Association of American Physicians & Surgeons* v. *Weinberger* only because the New York statutes now are more carefully drafted, assuring even greater confidentiality. The same reason that caused this Court to affirm the *Weinberger* warrants rejection of a privacy claim, and is persuasive that the District Court's judgment be reversed. That appellees fear the confidentiality provisions may be ineffective is not properly before the Court. Even the liberal approach to standing and case or controversy indicated by *Flast* v. *Cohen,* 392 U.S. 83, a First Amendment case and its progeny, will not justify a fear that a statute may be violated, when there can be no showing that there is either an actual or inevitable abuse of the reporting process. Furthermore, the thirty year history of non-abuse of similar filing requirements in California, Illinois and Idaho, indicates both that appellee's fears are unfounded and that the New York confidentiality provisions are an adequate safeguard of the right of privacy. A claim that state officials will disclose confidential information, when a statute prohibits it is usually treated as frivolous and unrealistic. See *Sanders* v. *Wyman,* 464 F. 2d 488, 491, n. 3 (2d Cir. 1972). *cert. den.* 409 U.S. 991. This is properly the situation here.

B. The purpose and operation of the filing system will not lead to disclosure or stigmatization

The purpose of the challenged statutes must be determined within the contextual purpose of Article 33. Its general purpose is to provide a comprehensive system of regulating dangerous drugs, which are intended for lawful medical purposes, but are frequently unlawfully and carelessly abused thereby presenting an immediate danger to the unsuspecting or unlawful user, as well as a more abstract yet real danger to the general public health, safety and welfare. As part of this comprehensive scheme, the legislature classified dangerous drugs into five schedules. The system of classification is not here under review, the District Court's dismissal of that issue having been affirmed by the Court of Appeals (480 F. 2d 102). The sections of

the Public Health Law here in issue [§§ 3331(6); 3332(2)(a) and 3333(4)] pertain to the use and filing of special triplicate prescription forms for Schedule II drugs. These drugs include various amphetamines, morphine and methadone (narcotic and psychotropic). Here the emphasis is not on controlling street abuse of contraband drugs, but rather on controlling "the growing trends of diversion and legitimate abuse of dangerous drugs"; *Interim Report of the Temporary State Commission to Evaluate the Drug Law,* State of New York, Legislative Document #10 (1972) p. 22. Only by filing and subsequent computerized use of the data on the triplicate prescription form, can the state efficiently regulate the abuse of dangerous, yet medically useful drugs.

There is no reasonable specter of major print-outs correlating patients with particular drugs (87a). Since the prescription form does not require any diagnosis or listing of malady, this imaginary ghost that the appellees envision is clearly beyond the realm of possibility. The programmed use of the computers which utilize patient's names will print-out only instances of potential abuse. Appellee patients contend they are not abusers. Only by filing the patient's name can the serious abuses of going from doctor-to-doctor, over-prescription by the same doctor and forgeries be detected and regulated. Forgers will frequently use the same name, go to different doctors and different pharmacists and thereby be detected only if patient identity is available.

The lower court's language concerning the supposed effectiveness of the filing not only was a novel approach to testing a statute's constitutionality, but was based upon an unfair examination of the filing operation. In every computer system it takes many months before the mechanism is programmed properly and functions efficiently. Because of the protracted litigation in this case, the Department of Health has still been prevented from working out all the

errors in the system, thereby making optimal functioning impossible even at the time of trial. Furthermore, the use of any one month's data is certainly not statistically significant due to expected monthly fluctuations. Extensive preliminary data indicate that use of patients' names and addresses is the only viable method of efficiently spotting drug abuse as manifested by going from doctor-to-doctor, over-precription by one doctor, and forgeries.* To deny the State use of the triplicate drug prescription, including the patient's name and address is to deny the State use of the only efficient means of controlling a significant type of abuse of dangerous drugs. This is particularly paradoxical since the State's right to gather the same information by going from pharmacist to pharmacist as is presently done is not challenged by this action and is presumptively constitutional.

The purpose of the statute is to control drug abuse, not to abuse patients. Computers are to be used consistently with individual freedoms and to protect the individual's and the public's health welfare. Filing and computerization (electronic processing) of names and addresses of patients does not restrict either individual freedoms or the medical decision to prescribe Schedule II drugs. Modern methods of computerization using patient identity (names and addresses) will help control the abuse of dangerous drugs. This abuse can result in severe psychological and physical dependence.

The confidentiality provisions of Public Health Law § 3371 and the time limitations of P.H.L. § 3370 further

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* In a computer run made several months ago of one month's filing, 45 cases of potential abuse were spotted because use of the patient's name and address allowed the computer to identify instances of going from doctor-to-doctor, over-prescription by a single doctor, and possible forgeries and stolen prescription forms where such blank forms had previously been reported by doctors are lost or stolen. *Supra,* pp. 27, 29 (ftn.).

guarantee that any data will be properly used by statutory and ethical requirements of honoring the individual's right of privacy. There is no danger of either disclosure or stigmatization. It is antithetical to the living nature of the Constitution to hold that a legitimate state purpose should be condemned because of the carefully restricted use of modern technology.

This Court has indicated that the state could use efficient means in securing legitimate purposes. In *Rosario* v. *Rockefeller,* 410 U.S. 752, at 762 fn. 10, the Supreme Court said that:

> "We agree with the Court of Appeals [2d Circuit] that '(i)n requiring that the state use to a proper end the means designed to impinge minimally upon fundamental rights, the Constitution does not require that the state choose ineffectual means', 458 F. 2d, at 654".

C. The physician-patient relationship is not a *per se* prophylactic of the right of privacy

The physician-patient privilege did not exist in modern common law. Approximately two-thirds of the states have statutorily created some type of physician-patient privilege to protect "those communications which are necessary for obtaining the lengths of the professional relation". 8 J. Wigmore, Evidence § 2383 at 842 (J. McNaughton ed. 1961). At least one-third of the states, and the Federal Rules of Evidence (501) have no physician-patient privilege at all. Most of the states that have created the privilege have qualified the privilege so that it does not always apply. In New York, there is no physician-patient privilege in certain proceedings under the Family Court Act, N.Y. (Judiciary Law), Family Court Act, § 1046(a)vii; there is an affirmative duty to report information indicating that a patient under age sixteen has been a victim of a crime, N.Y. Civil Practice Law and Rules, CPLR 4504(b); to report every case of cancer or other malignant disease, P.H.L. §§ 2401, 2402; to report gunshot wounds and other wounds that may result in death, N.Y. Penal Law § 265.25. In respect to enforcement of Article 33 herein, P.H.L. § 3373 specifically provides that the privilege shall not exist under Article 33. It should be obvious that the physician-patient relationship is not so constitutionally protected so as to dictate that the physician-patient evidentiary privilege be constitutionally mandated. Instead, the determination of whether or not there should be a physician-patient privilege, and when such a privilege should attach, is within the sole discretion of the state legislature as reserved by the Tenth Amendment to the Constitution. *Katz* v. *United States,* 389 U.S. *supra,* at 350-351 (1967).

Whether or not a state should create a physician-patient privilege is not a proper subject of judicial review, *Matter of N.Y.C. Council* v. *Goldwater,* 284 N.Y. 296, 302, 31 N.E. 2d 31, 33 (1940). Nevertheless, the determination of the legislature in excluding the privilege from Article 33, can be readily supported. First, it is unlikely that a person's identity is a communication that originates in confidence. The supposed confidentiality is immediately belied by the necessary communication of the information to the pharmacist. Indeed, the appellees do not question (at least in this action) the state's right to go through pharmacist's files on all prescriptions which entails a broader disclosure than the selective filing of prescriptions of dangerous (Schedule II) drugs. Secondly, even if the communication did originate in confidence, the state's interest in controlling drug abuse must surely outweigh any potential injury to the relationship. The disclosure to the Department of Health is thoroughly protected by the confidentiality safeguards and time limitations of P.H.L. §§ 3371 and 3370. There is no foundation for questioning the legislature's determination that the legitimate state interest in regulating the prescription of dangerous drugs is more compelling

than the marginal value of the physician-patient privilege in the context of prescribing dangerous drugs. Finally, it is unlikely that the filing requirements of the challenged statutes infringe upon the attainment of the benefits of the professional relation. There is some human propensity to disclose our various ailments and the drugs we use for relief. Although Schedule II drugs are uniformly dangerous, use of these drugs is not infrequent.* For instance, demerol is a Schedule II drug which is commonly prescribed and widely discussed. Although appellees raise the specter of stigmatization, they have shown nothing more than an unsubstantiated fear of stigmatization, a fear founded in ignorance as the record herein shows. It is unlikely that an individual who actually requires a Schedule II drug would be dissuaded from taking the drug if the individual understood the purposes and restrictions on use of the filing requirement which the record shows they did not. It is impossible for New York to create a statute that will reflect the individual psyches of eighteen million people. Article 33 represents the legislature's considered judgment of how to maximize the public health, safety and welfare while minimizing the risk of potential injury to the individual by explicitly providing for the confidentiality of the records and by allowing the doctors to make the ultimate decision as to what drug to prescribe for a condition.

From the above, it is evident that the doctor-patient privilege does not and should not apply to Article 33. The statute specifically so provides. P.H.L. § 3373. It is not contended that the doctor-patient privilege is necessarily equivalent with the physician-patient relationship. However, the "privilege" is the only practical manifestation of the relationship. That the "privilege" does not uniformly exist, and exists only within certain boundaries of use, indicates that the "privilege" does not stem from a fundamental relationship. It is difficult to compare the often transitory physician-patient relationship to the sanctity of the marital and family relationships which the Supreme Court has indicated as fundamental. By placing an inappropriate sanctity on the abstract physician-patient relationship, without considering the actual restrictions on the physician-patient privilege, the lower court has focused on an inappropriate concern.

* As witness the over 100,000 filed prescriptions each month. But much is for non-medical purpose. 73 Col. L. Rev., *supra* at 380, fn. 22.

In summary, the opinion of the three-judge court relied heavily on an abstract and unsubstantiated fear of disclosure and consequential stigmatization in concluding that the challenged statutes violated the individual's right of privacy. The court seemed to ignore the restrictions on the privilege which is the sole practical expression of the physician-patient relationship. The court failed to appreciate that the purpose and operation of the statute is antithetical to the mass disclosure and stigmatization which appellees fear. Finally, the lower court failed to take account of the statute's confidentiality provisions which on their face absolutely minimize the risk of an invasion of privacy. These three factors demonstrate that the three-judge court erred in finding that P.H.L. §§ 3331(6), 3332(2)(a) and 3333(4) violated the individual's right of privacy.

VI. The appellees failed to present a real case or controversy and thus lacked standing to maintain the action simply as prescribers and users of dangerous drugs.

While it is not disputed that appellees are patients who receive Schedule II dangerous drugs and doctors who prescribe same, the issue that they purport to present, i.e., that filing of Schedule II prescriptions with appellants violates their constitutional rights is a spurious creation. Simply because they fear misuse or stigmatization, this does not create a "real case or controversy." As an undifferentiated

fear, lacking any specific injury (appellees failed to show any misuse of data as to them or anyone else) the instant action has an "underlying fallacy". As said in *Roe* v. *Ingraham,* 364 F. Supp. 536, 545 (S.D.N.Y. 1973) (three-judge court):

> "*Thom* [306 F. Supp. 1002, affd. 425 F. 2d 1074, *cert. den.,* 398 U.S. 905] emphasizes once again the underlying fallacy of plaintiffs' argument. Any invasion of privacy which occurs under this statute would appear to result from the original insertion of a patient's name on the prescription and its delivery to the pharmacist rather than the centralized collection of these documents".

In other words, centralized collection, as a means of furthering a legitimate state objective, is not an invasion of privacy and thus any challenge to same does not present a real case. Obviously access by appellant's personnel to prescriptions including patient identity is absolutely vital to controlling use of these dangerous drugs. "How" is not really an issue.

Yet in the final opinion of the District Court it was necessary to assume that an undifferentiated "fear" of computerization gave standing or created a real case for the plaintiff patients and doctors to challenge not just computerization but the filing of the triplicate prescriptions themselves. Thus it was stated (J.S. 10a):

> "When these physical illnesses and disabilities require as here treatment by drugs which, in light of the current epidemic of drug abuse in the society, are under governmental control and regulation, there is legitimate concern that information that one, one's children or an intimate is under treatment with such drugs not be broadcast to unauthorized sources. There is fear that the adults or children will be stigmatized if their use of the drug becomes known. There is no question but that the statutory requirement challenged here intrudes upon and interferes with the doctor-patient relationship."

Yet there was absolutely no testimony at trial that the information would or could be "broadcast to unauthorized sources" (§ 3371 prohibits unauthorized disclosure). The opinion could only state the "fear" of stigmatization, *supra.* On the other hand the state effort to control drug abuse and prevent illicit trafficking in dangerous drugs was and is a legitimate state purpose. Despite this the Court concluded that the statute intruded on the doctor-patient relationship and had a needlessly broad sweep. In this regard it had to use the "compelling state interest" test, and expanded it beyond the decisions of this Court, *supra* (II and III). Courts are not to apply the fundamental-interest analysis lightly. *San Antonio Ind. School District* v. *Rodriguez,* 411 U.S. 1, 18, 44 (1973).

Ignored in the opinion is the fact that the law protects confidentiality by limiting strictly the information, as well as the possible uses of that information; P.H.L. § 3371. This negates any invasion of privacy. The decision also ignored the plain legal facts of the original decision. To quote, 357 F. Supp. 1217, at 1221:

> "First, this is not a case where the state has launched a broad scale invasion into the doctor-patient relationship requiring the publication of the entire medical history and treatment record. Indeed, contrary to plaintiffs' suggestion, even the illness for which the Schedule II drug is prescribed need not be revealed.
>
> "Second, the statute *on its face* does not permit unrestricted divulgence of even the limited information collected. In fact § 3371 confines disclosure to the extent consistent with the purpose of the Act. I have also been presented with the memorandum of Assem-

blyman Hardt and the affidavit of Commissioner Whalen, both of whom appear to be taking all necessary steps to maintain the security of the computerized information.

"Finally, this is not a case where the plaintiffs have been able to prove actual abuse of the reporting and computerizing process and consequently to argue facial unconstitutionality based upon pragmatic or historical evidence; that is that such process necessarily and inevitably results in abuse." (emph. suppl.)

Appellees' testimony at trial clearly showed they simply were ignorant of the law's confidentiality provisions (P.H.L. § 3371); and of the five year limitation on records; or the State had ever "broadcast" their records, in any manner. There can be no doubt that the appellee patients were not failing to receive medication due to the statute or any of appellant's action. Clearly the statute infringed no "fundamental interest" or the ability to receive medication.

The appellees were ignorant of the fact that appellant always had access to their prescriptions, even before the passage of the statute involved. Once again the Court ignored this obvious point in the final decision which negates any impermissible invasion of a constitionally-protected right by reason of this statute. The failure to advert to this is anomalous in view of its recognition in the earlier opinion in this case in which the single district judge said in dismissing the complaint (357 F. Supp. 1217, at 1221-1222):

"In order to further appreciate the essence of plaintiffs' privacy argument, it is necessary to consider the status of the law prior to April 1, 1973. Insofar as the issues involved in this lawsuit are concerned, the only effective distinction is that the new statute requires sending a copy of each prescription for Schedule II drugs to Albany to be computerized. Previously

prescriptions required the name of the patient, N.Y. Public Health Law § 3301(32) (McKinney 1971) (repealed 1973), the pharmacist was required to keep a copy of the prescription, *Id.* at § 3322, and law enforcement officials had complete access to the druggists' prescription files, *Id.* at §§ 3322(1)(c), 3334. In short, the state had the power to learn all that it may now require to be revealed. The only difference is that now the state has developed the means to *make effective use* of that basic power which remains unchallenged." (Emphasis supplied) See also *Roe,* 364 F. Supp. at 544.

It was only by ignoring these obvious points that the three-judge court could conclude that the appellees had a real case. It even had to ignore its own prior decision, 364 F. Supp. 536, finding "no evidence of any immediate injury", *id.* at 546, see also 545. The plain fact was that after some 15 months of computerization, at time of trial (December, 1974), no appellee or anyone else, could show any injury from filing or computerization, or appellant's operation thereof.

On the other hand, the decision undercuts the ability to control drug abuse, a fact of life to thousands of people, many of them the recipients of Schedule II drugs, ostensibly for medical purposes. This was a strong factor in the three-judge court originally allowing filing to go forward. 364 F. Supp., at 546:

"It should be noted, however, that the state's efforts are directed against a very real and pressing emergency requiring immediate and effective response."

The decision however ignored this "emergency", what was obviously an immediate and effective plan and appellees' baseless fears were given the force of law. To condemn computerization because of its efficiency strikes at many vital governmental functions and efficiency is not a constitutional vice. *Rosario* v. *Rockefeller, supra.*

As we have pointed out a vague "fear" does not support a cause of action. *Laird* v. *Tatum, supra,* 408 U.S., at 13-14. What makes this an even stronger case than *Laird,* is the fact that the filing and computerization herein is authorized and controlled by a specific statute directed to a specific and real problem. This is not a case of bureaucrats administratively setting up a computer data-bank. Rather the Legislature saw the need for this compilation and passed specific legislation after much study. (See Interim Reports of Temporary State Commission to Evaluate the Drugs Laws).

The "danger" to plaintiffs was and is hypothetical, based on unsupported assertions that the clear provisions of the very law they are challenging would not be observed—as to confidentiality and length of recordkeeping. (P.H.L. §§ 3371 and 3370).*

The decision ignored the testimony that other public officials such as school personnel had records of children taking ritalin, a Schedule II drug. (This drug apparently reduces hyperkenesis, but also has serious side effects) (173a).

Remote claims of risk of disclosure do not support a cause of action. *California Bankers Ass'n.* v. *Schultz,* 416 U.S., at 56-57, *supra.* This case upheld a federal bank recordkeeping and reporting statute against constitutional challenge.

While standing has been expanded by this Court, it is the law that pleadings (and proof) "must be something more than an ingenious academic exercise in the conceivable." *United States* v. *SCRAP,* 412 U.S. 669, 688 (1973):

> "A plaintiff must allege that he has been or will in fact be perceptibly harmed by the challenged agency

* The veneer of "expert proof" herein (Wasserman and Rosenberg) bore no relationship to appellees' fears. It cannot repeal P.H.L. §§ 3371 and 3370.

> action, not that he can *imagine* circumstances in which he could be affected by the agency's action. And it is equally clear that the allegations must be true and capable of proof at trial." (Emphasis supplied).

The "proof" in the instant case was that the appellees "imagined" harm and took action on such "visions" (123a-124a). Yet with one or two exceptions all received their medication, negating interference with medical practice. Any refusal to accept medication was based on a self-fulfilling prophecy that at some time in the future the data on prescriptions would be misused. It was a personal decision, foisted on patient appellees by appellee doctors who had an irrational antagonism to filing. Such absurd reasoning cannot support a case. Courts do not engage in vacuous speculation that public officials may not observe statutes or regulations as to confidentiality. *Sanders* v. *Wyman, supra,* 464 F. 2d 488, 491, n. 3. Even "fears" as to others do not give standing. *Moose Lodge No. 107* v. *Irvis,* 407 U.S. 163, 166 (1972).

Certainly *California Bankers Ass'n., supra,* at 68-69, gives no support to conjectural pleading and proof which is all the instant case contains. Testimony that because of "fears", a patient decides not to take a drug hardly supports a claim that filing injured appellees. "Injury in fact" is necessary. This should be specific and distinct. *Schlesinger* v. *Reservists Comm. to Stop the War,* 418 U.S. 208, 216-227 (1974). Appellees have no more interest than anyone else in the actions of appellant, as they assert they are not the targets of the effort to control drug abuses.

The district court struck down an important part of a legitimate state statute on the basis that anonymous patients *might* be harmed by filing *if* the state did not observe the statute (P.H.L. § 3371) as to confidentiality. Also ignored was the five year limitation on keeping of records (P.H.L. § 3370[3]) which obviously shows that no one is

branded for life, or that a child, years later, could have his prescription records revealed. The "fears" which allegedly gave standing or reality to this case, were legally without substance.

CONCLUSION

The judgment below should be reversed.

Dated: New York, New York, May 17, 1976.

Respectfully submitted,

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APPENDIX

New York Public Health Law (P.H.L.) §§ 3331(6), 3332(2)(a), and 3333(4)

There are:

P.H.L. § 3331 (6):

"6. A practitioner dispensing a substance which may be prescribed only upon an official New York state prescription must at the time of such dispensing prepare an official New York state prescription in the manner set forth in subdivision two of section thirty-three hundred thirty-two of this article. The practitioner shall retain one copy for five years and shall file the original and one copy with the department by not later than the fifteenth day of the next month following the month in which the substance was delivered. This requirement shall not apply to the dispensing by a practitioner pursuant to section thirty-three hundred fifty-two of this article."

P.H.L. § 3332 (2) (a):

"2. Such prescription shall be prepared in triplicate, written with ink, indelible pencil or, apart from the practitioner's signature, typewriter. The original and both copies must contain the following:

(a) the name, address and age of the ultimate user for whom the substance is intended, or, if the ultimate user is an animal, the species of such animal and the name and address of the owner or person in custody of such animal;"

P.H.L. § 3333 (4):

> "4. The endorsed original prescription shall be retained by the proprietor of the pharmacy for a period of five years. The endorsed copy of such prescription shall be filed with the department by not later than the fifteenth day of the next month following the month in which the substance was delivered."

Other portions of Article 33 of the New York Public Health Law are possibly involved and are set forth at J.S. 20-a to 38-a.

Supreme Court, U. S.
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Supreme Court of the United States

OCTOBER TERM, 1975

No. 75-839

ROBERT P. WHALEN, as Commissioner of Health of the State of New York,

Appellant,

against

RICHARD ROE, an infant by ROBERT ROE, his parent; JOHN DOE, an infant by MARY DOE, his parent; JAMES MOE, an infant by MICHAEL MOE, his parent; JANE POE, MATTHEW T. BRODY, ISRAEL L. SCHMIERER and EMPIRE STATE PHYSICIANS GUILD, INC.,

Appellees,

and

GEORGE PATIENT, MARTHA PATIENT, GERALD L. LUSTIG, and THE AMERICAN FEDERATION OF PHYSICIANS AND DENTISTS,

Intervenor-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

APPELLEES' BRIEF

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Supreme Court of the United States

OCTOBER TERM, 1975

No. 75-839

ROBERT P. WHALEN, as Commissioner of Health of the State of New York,

Appellant,

against

RICHARD ROE, an infant by ROBERT ROE, his parent; JOHN DOE, an infant by MARY DOE, his parent; JAMES MOE, an infant by MICHAEL MOE, his parent; JANE POE, MATTHEW T. BRODY, ISRAEL L. SCHMIERER and EMPIRE STATE PHYSICIANS GUILD, INC.,

Appellees,

and

GEORGE PATIENT, MARTHA PATIENT, GERALD L. LUSTIG, and THE AMERICAN FEDERATION OF PHYSICIANS AND DENTISTS,

Intervenor-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

APPELLEES' BRIEF

This is a direct appeal from the final order and judgment entered on October 9, 1975 by a district court of three judges constituted pursuant to 28 U.S.C. §§ 2281 and 2284 (J.S. 18a).* The final order and judgment declared unconstitutional and enjoined enforcement of three specific provisions of Article 33 of the New York Public Health Law

* Numbers in parentheses preceded by "J.S." and followed by "a" refer to pages of the appendix following appellant's Jurisdictional Statement herein. Numbers in parentheses followed by "a" refer to pages of the appendix. Numbers in parentheses preceded by "Ex." refer to plaintiffs' exhibits. Names in parentheses followed by the abbreviation "Tr. Dep." and a number (e.g., Bonacci Tr. Dep. 41) refer to pages of trial depositions considered by the Court pursuant to Consent Pre-Trial Order No. 2 (*infra*, p. 6, fn. and Addendum) but not included in the appendix.

(hereinafter "Article 33" or the "Act")—§§ 3331(6), 3332 (2)(a) and 3333(4)—"insofar as they require disclosure to the State of New York of the identity of patients receiving prescriptions for Schedule II controlled substances" (J.S. 14a-17a at pars. 1, 2). In addition, the judgment directed the destruction of New York prescription forms previously filed pursuant to the statute, the expungement of patients' names from records made from the prescription forms and the filing of an affidavit describing the time, place and manner of such destruction and expungement (J.S. 14a-17a at pars. 3, 4). At the request of the State, a stay of the paragraphs of the judgment relating to destruction of the records and expungement of patients' names was granted by the three-judge court pending disposition of appellant's appeal or other order of this Court (J.S. 16a at par. 5). The State's applications for a broader stay were denied by the three-judge court on October 20, 1975 (6a, 8a) and by Justice Marshall on October 28, 1975 (J.S. 39a-43a, *Roe* v. *Whalen* (opinion in chambers), —U.S.—, 46 L.Ed. 2d 18 (1976)).

Statement of the Case

Prior Proceedings

Proceedings prior to trial herein are set forth in the three reported opinions, *Roe* v. *Ingraham,* 357 F. Supp. 1217 (S.D.N.Y. 1973) (32a-40a) *rev'd.* 480 F. 2d 102 (2d Cir. 1973) (41a-54a), on remand 364 F. Supp. 536 (S.D.N.Y. 1973) (three-judge court) (57a-76a) and in Appellee's Motion to Affirm herein (pp. 3-4). The trial was held in December, 1974, pursuant to Consent Pre-Trial Order No. 2 made on November 21, 1974 which provided that the trial testimony of plaintiffs' expert witnesses and defendant's witnesses would be submitted to the Court in

deposition form, and that the remainder of the trial would take place before the three-judge court (Addendum at pp. A-1-A-2).

On August 13, 1975, the three-judge court filed its unanimous opinion holding that "so much of the New York Health Law as requires reporting to state authorities in Albany the names and addresses of patients who receive Schedule II drugs as medication prescribed by duly licensed physicians is an unconstitutional interference with plaintiff's right of privacy guaranteed under the Fourteenth Amendment" (J.S. 13a). The opinion is reported as *Roe* v. *Ingraham,* 403 F.Supp. 931 (S.D.N.Y. 1975).

The Court noted that "[a]n individual's physical ills and disabilities, the medication he takes, the frequency of his medical consultation are among the most sensitive of personal and psychological sensibilities" (J.S. 10a); recognized that "there is legitimate concern that information that one, one's children or an intimate is under treatment with such drugs not be broadcast to unauthorized sources" (J.S. 10a); stated that "the state effort to control drug abuse and to prevent illicit trafficking in dangerous drugs fosters a legitimate state purpose" (J.S. 11a); found that "admittedly the only purpose this information [names. addresses and ages of patients receiving Schedule II drugs] serves is to identify individual patients who without using an alias go from doctor to doctor to secure Schedule II drugs and those individuals who secure more than a 30-day supply in any single month" and that "[d]uring the 20-month life of the program only one such unresolved incident in this category has been unearthed" (J.S. 11a); and held that "[t]he diminution of a constitutionally guaranteed freedom is to great a price to pay for such a small governmental yield" (J.S. 11a). 403 F. Supp. at 937.

Plaintiffs' Claim

Roe, et al. v. *Ingraham* was brought by four patients,* including three infants and one adult receiving medications set forth in Schedule II of § 3306 of the New York Public Health Law (hereinafter "Schedule II drugs") (10a, 114a-115a, 137a, 170a-171a, 211a-212a), two named doctors who prescribed such drugs (10a, 146a-148a, 184a-185a), and The Empire State Physicians Guild, Inc., a New York Membership Corporation representing the interests of certain New York physicians (10a, 185a).** *Patient, et al.* v. *Ingraham* was brought by a post-operative cancer patient and an individual suffering from migraine headaches, both of whom received Schedule II drugs as medication (15a, 140a-143a, 195a-198a), the doctor of one of these patients (15a, 203a-210a) and The American Federation of Physicians and Dentists (15a).

The gravamen of plaintiffs' claim was that certain provisions of Article 33 are unconstitutional insofar as they require physicians and pharmacists to file with the State of New York prescriptions revealing the identity of patients using Schedule II drugs. The challenged provisions require (a) that all Schedule II drugs be prescribed on prescription forms containing, *inter alia,* the name, address and age of

* The State asserts that the patient plaintiffs are "anonymous" (Appellant's Br., p. 5). This is incorrect. The identity of the patient plaintiffs was provided to defendant and the Court below and all plaintiffs testified in open court during the trial. To protect their privacy, however, the Court permitted such plaintiffs to prosecute the action under pseudonyms (113a-114a).

** It is respectfully submitted that the State's allegations regarding the Empire State Physicians Guild, Inc. and the "financial backing" of the instant action (Appellant's Br., p. 5, fn. (*)) go beyond irrelevancy and immateriality to constitute scandalous matter which could properly be stricken under Rule 40(5) of the Rules of this Court. The matter was fully aired on numerous occasions in the lower courts and again at length on the application to Justice Marshall for a stay (see Appellees' Memorandum in Opposition to Application for a Stay of Judgment at pp. 29-30; see also 164a-167a).

the patient (§3332(2)) and (b) that copies of such prescription forms for Schedule II drugs, which in every case contain the identity of persons using the medication, must be sent to the Department of Health of the State of New York each and every time they are prescribed (§§3331(6) and 3333(4)). Plaintiffs contended that the foregoing provisions violate the Fourteenth Amendment of the United States Constitution in that they unnecessarily invade the patient's right of privacy and the doctor's right to prescribe treatment for his patients solely on the basis of medical considerations.

Operation of the State's System

The information acquired by the State is "coded" into a centralized computer and used in enforcement of Article 33 (91a-98a). The Act contains no limitation on the sweeping requirement that copies of all prescriptions for Schedule II drugs (including thereon the names of the patients) must be filed. There is no provision for any summons, either judicial or administrative, as the means whereby the Department of Health is required, in the usual case, to demand reports from doctors and pharmacists. The Department of Health is required by the Act to demand and obtain such reports routinely, automatically, from all physicians and pharmacists in the State without any process whereby physicians or pharmacists or patients may test in advance the reasonableness of the demand. Until entry of the final order and judgment below, approximately 125,000 prescriptions were received each month by the State (474a) and were coded into the computer by a staff of over 30 persons—seventeen clerks to open, code, sort and batch the forms in preparation for computerization (484a) and fourteen key punch operators (92a at par. 5).

At the trial, testimony by Dr. Arthur G. Baker (hereinafter "Dr. Baker"), Associate Commissioner of

Health for Community Health Services was received into evidence (Ex. 37).* Dr. Baker has overall responsibility for the triplicate prescription program (91a). Two Bureaus under his jurisdiction have responsibilities relating thereto —the Bureau of Narcotic Control (hereinafter "BNC") and the Bureau of Controlled Substances, Licensing and Evaluation (hereinafter "BCSLE") (91a). The BNC, under its director, John J. Bellizzi (hereinafter "Bellizzi"), is responsible for conducting investigations of alleged violations of Article 33. The BCSLE, under its director, Joseph L. Cannizzaro (hereinafter "Cannizzaro"), is responsible for processing filed prescriptions, security and retention of the triplicate prescription information and transmitting such information to the BNC (91a). In addition, the Office of Electronic Data Processing ("OEDP") participates in processing the prescriptions by transferring the information from the prescription blanks to discs to tapes which can be "read" by the computer (91a-92a). The director of OEDP, since March 1974, has been Joseph Bonacci, and prior thereto was Harold Gottheim (92a).

Although many printouts were issued by the State's System (95a-97a), the only printout containing patient names was a printout setting forth the names of patients with prescriptions of Schedule II drugs totaling in excess

* Because it was not included in the Appendix prepared by Appellant, we have set forth in full as an Addendum to this brief Pre-Trial Order No. 2 on Consent filed in the Court below on November 22, 1974 (3a). As appears therefrom (see Addendum, *infra*), it was stipulated by the parties and ordered by the Court that only the testimony of the plaintiffs would be heard in open court by the three-judge panel, with the remaining witnesses and exhibits submitted in the form of depositions. There were few objections to such exhibits and testimony and, in any event, by its order of July 28, 1974 (5a) and its opinion herein (364 F.Supp. 536 [S.D.N.Y. 1973]; 57a-76a), the Court received in evidence all such trial depositions and exhibits. Portions of the pre-trial deposition testimony of Dr. Baker were one such exhibit.

of a 30-day supply processed in one month (422a-423a).* Dr. Baker confirmed that this was the only information from the computer which would contain patients' names (95a, par. 12) and that its only purpose was to assist in the identification and investigation of persons who, using the same name, go from doctor to doctor to obtain an illicit supply of Schedule II drugs (95a, par. 12; Ex. 37, p. 139). Patients' names on the computer do not assist in detecting forgeries (Ex. 37, pp. 118-20), raised prescriptions (Ex. 37, p. 129), thefts (Ex. 37, p. 126), over-prescribing or over-dispensing (Ex. 37, pp. 120-21, 126-129). Such violations are currently being detected by printouts which do not use patient names (504a-511a; Ex. 14-16). Thus, the State has stipulated that the only purpose of requiring patients' names on the prescription forms filed with the defendant is to assist the State in identifying "persons who, using the same name, go from doctor to doctor to obtain an illicit supply of Schedule II drugs" (95a, par. 12).

The number of case reports of such violations was as follows from January 1, 1969 to May 12, 1974 (95a, par. 12):

1974	1 case
1973	None
1972	None
1971	1 case
1970	1 case
1969	1 case

* In addition, it was revealed for the first time at the trial, and contrary to the stipulated facts (95a, par. 13) that BNC also receives printouts when it requests information relating to a particular subject under investigation (423a-424a). No evidence was offered as to the criteria used in determining whether BNC should receive such printouts or the aid, if any, to BNC investigations resulting from such printouts. As of May 21, 1974, when he testified on deposition in this case, Mr. Bellizzi said that the computerized information had been of no use whatever to BNC (98a, par. 16).

Since May 1974, BCSLE, under Mr. Cannizzaro, has uncovered one additional patient, by use of the computer, who had possibly gone from doctor to doctor to obtain excessive amounts of drugs within a 30-day period and referred his name to BNC (97a, par. 15). Thus, the computerized system uncovered a grand total of two patients who may have gone from "doctor to doctor" to obtain excessive amounts of Schedule II drugs. The two referrals were investigated by BNC. One investigation disclosed a *bona fide* patient relationship (97a-98a, par. 15). The other was still pending at the time of trial (*id.*). There was no evidence that any of the three prior case reports in 1969, 1970 or 1971 had resulted in any enforcement action by BNC (*id.*).

Adequacy of the Provisions to Protect Against Malicious or Careless Disclosure

The triplicate prescriptions were processed on a Burroughs 3500 computer, which was to be replaced by a Burroughs 6700 computer (98a, par. 17). There are approximately 22 terminals that have access to the computer (Bonacci Tr. Dep. 77) but at present not to the triplicate prescription data. However, adjustments to the computer which would permit such access could be completed within two or three weeks after they were authorized (Bonacci Tr. Dep. 39-40; Ex. 40, p. 85).

Joseph J. Wasserman, an acknowledged expert in the security of computerized data (297a-300a; Ex. 41), examined the State's computer facility in Albany and concluded that, because of inadequate security, there is a substantial risk of unauthorized disclosure of the triplicate prescription information (321a). His testimony was uncontradicted.

Effects on Plaintiffs

Doctor plaintiffs observed the injuries to their patients directly resulting from fears of the effects of the Act's filing requirements (154a, 186a-187a). One plaintiff, a neurologist and psychiatrist, terminated treatment by use of Schedule II drugs for 15 to 20 patients suffering from schizo-affective mental disorders, even though such drugs were medically indicated and highly beneficial, because the patient-physician relationship would be endangered by the suspicions created (154a-155a, 168a-169a). Others found that a large number of patients refused to continue using Schedule II drugs upon learning of the filing requirements (177a-181a, 186a-187a, 211a-214a). Yet another physician refused to prescribe Schedule II drugs, even to relieve pain after surgery, because of his apprehension of misuse of the filed information (203a-208a).

All the patient plaintiffs feared massive computerization by the State (114a-118a, 138a, 140a-143a, 170a-171a, 211a-212a). One patient plaintiff first tried substitute drugs and, when they did not yield satisfactory results, he obtained the required medicine in New Jersey where the information would not be put on a computer (196a-197a). Another patient plaintiff disregarded the advice of her son's pediatrician and refused to permit her son to continue receiving prescriptions for Schedule II drugs when she learned that the prescriptions therefor containing his identity would be placed on the State's computer in Albany (170a-172a).

The disturbing psychological effect of awareness by an individual that the State is accumulating personal data about him is well known. When such awareness occurs in the stressful context of a patient seeking aid from a physician, the harmful effect is heightened (249a-250a, 255a). A highly qualified psychologist (234a-239a) described such

effects which include increased incidence of conforming behavior and withdrawal, lowered productivity at school or work, fear of government and physical symptoms (240a-252a). The evidence is uncontradicted that patients' apprehensions of centralized massive filing will have a substantial negative psychological impact on a significant number of persons (252a-253a).

Legislative History of the Act

The legislative history of the Act*, as detailed in Point III A 1, *infra,* reveals that no consideration at all was given to the question whether there is any need for the filing and computerization of patients' names. Most of the legislative history is devoted to provisions of Article 220 of the Penal Law (enacted together with Article 33) and to provisions of Article 33 not challenged hereby or relevant to this case. In the rare instances where the triplicate prescription provisions are discussed—principally on two pages of the 1972 Interim Report (Ex. 32, pp. 21-2) and the Hardt Memorandum (Ex. 33)—the discussion consists of generalized and unsupported claims that they will assist in enforcement of the Act. Thus, the 1972 Interim Report states that the objects of the triplicate prescription provisions are to enable the Department of Health "to compile data which will uncover irregularities such as forgeries, fraudulent obtaining of schedule II substances, and thefts of prescription blanks and their misuse by unauthorized persons" and to enable the Department to determine "if a patient has

*Hearings were held by the Temporary State Commission to Evaluate the Drug Laws which issued interim reports in 1971 (Ex. 31) and 1972 (Ex. 32, pp. 96-134). In addition, shortly prior to passage of the bill by the New York State Legislature, Chester R. Hardt, Chairman of the Temporary State Commission, issued a memorandum (Ex. 33) (hereinafter the "Hardt Memorandum"). It was stipulated that, for purposes of this action, these three documents constitute the legislative history of the Act (81a-82a).

obtained prescriptions by going from doctor to doctor, or if stolen prescriptions are being used" and "where there has been an over-prescribing or over-dispensing of schedule II drugs" (Ex. 32, p. 21). The Hardt Memorandum states that the triplicate prescription procedure is designed to reveal "physicians who have prescribed and dispensed a greater amount of a Schedule II substance than could possibly be justified by the nature of their practice" and "situations arising from lost or stolen prescriptions" (Ex. 33, p. 4).

The evidence in this case, as detailed in Point III A, *infra,* shows that, to the extent they suggest that patients' names are needed, such claims are baseless; that over-prescription, over-dispensing of drugs and abuses resulting from thefts and forgeries of prescription blanks can all be detected equally well without centralized filing of patients' names; and that the sole remaining abuse cited, the obtaining of illicit amounts of drugs by going from "doctor to doctor" is minimal. These facts were not considered by the legislature.

Nowhere in the legislative history is there any discussion as to whether the patient's name is required on the copy of the triplicate prescription form filed in Albany, whether accomplishment of the Act's objectives could be achieved equally well without the patient's name, whether the patient's identity is actually required in order to correct any abuse and, if so, whether the abuse cited is sufficiently widespread to warrant disclosure to the State of the patient's identity in the manner provided by the Act (see Ex. 31-33).

* * *

In summary, the evidence demonstrated a complete absence of any need for patients' names, and substantial risk of disclosure of such names to unauthorized individuals.

Summary of Argument

1. Decisions of this Court make clear that there exist constitutionally protected zones of privacy. In particular, *Roe* v. *Wade,* 410 U.S. 113 (1973), *Doe* v. *Bolton,* 410 U.S. 179 (1973) and *California Bankers Ass'n* v. *Shultz,* 416 U.S. 21 (1974), when read together, hold that the Constitution protects individuals from massive, automatic production of their intimate records to the state without judicial supervision. The centralized filing required under Article 33 is thus distinguishable from the production of designated records relating to one individual under investigation involved in such recent opinions of this Court as *Fisher* v. *United States,*——U.S.——, 96 S. Ct. 1569 (1976) and *United States* v. *Miller,*——U.S.——, 96 S. Ct. 1619 (1976).

Both judicial authority and the evidence in this case demonstrate that the statutorily required centralized filing of prescriptions for drugs required by thousands of individuals for legitimate medical reasons infringes three aspects of the right to privacy: (1) the "individual's interest in keeping to himself the existence of his physical ailments and his doctor's prescriptions for them" (*Roe* v. *Ingraham,* 480 F.2d 102 at 108; 51a); (2) the patient's "right to receive medical care in accordance with her licensed physician's best judgment" (*Doe* v. *Bolton,* 410 U.S. 179, 197 (1973)); and (3) "the physician's right to practice" (*id.* at 199).

Plaintiffs neither concede nor reach the question of whether prior New York State law which required pharmacists to retain copies of prescriptions and permitted state investigators to examine such prescriptions was unconstitutional. Rather they contend that whatever the constitutionality of prior practice, the instant procedure creates a far greater likelihood of invasion of privacy in that it requires automatic collection of vast volumes of

personal data by a centralized state agency without judicial supervision.

2. Intrusion by the state upon constitionally protected zones of privacy should be permitted only if justified by a compelling state interest. Furthermore, the relationship between the intrusion and the state interest allegedly served should not be based on mere conjecture of state officials but should be required to be demonstrated evidentially.

These requirements are particularly appropriate in the case of centralized, computer-assisted collection of medical data because of the personal and intimate nature of such data. Courts, legislatures, and commentators have increasingly recognized that the threat to privacy posed by computerized data systems requires new safeguards of individual rights in this area.

The State's assertions that affirmance of the lower court's judgment would result in a revival of substantive due process and would render all state statutes affecting the confidentiality of the doctor-patient relationship unconstitutional are baseless. The discredited doctrine of *Lochner* v. *New York,* 198 U.S. 45 (1905), permitted judicial scrutiny of legislative goals. Appellees in this case concede that control of dangerous drugs is a legitimate state goal, but contend that such a goal cannot legitimize massive intrusion into the private lives of individuals where the intrusion does not in fact serve the goal of controlling drug abuse.

3. Under either a compelling state interest or rational basis test, the instant statute's constitutionality cannot be sustained. The State has stipulated that the only need for centralized filing of patient names is to counteract the alleged problem of patients going to several doctors using the same name to obtain excessive amounts of Schedule II drugs (95a, par. 12).

In its brief in this Court, the State has (improperly) for the first time referred to alleged facts *dehors* the record supporting its claim regarding the seriousness of the "doctor to doctor" problem. However, at trial where the State had a full opportunity to develop such "facts", the uncontradicted evidence was that this problem has been insignificant historically (2 cases in 4 years). Neither does the legislative history of the Act give any support to the notion that this problem provides a basis for the centralized filing requirement. Furthermore, the federal government, the Commissioners on Uniform State Laws and the overwhelming majority of states which have considered triplicate prescription leglislation have not found it necessary to intrude upon the privacy of the physician-patient relationship by a filing requirement such as the one challenged hereby.

While appellees submit that the demonstrated lack of need for the challenged statutory provisions is decisive in the instant case, it has also been amply demonstrated that the State has failed to take reasonable precautions to maintain the security of prescriptions collected. Both published material and evidence in this case indicate that the executive branches of the federal and state governments have been unable to maintain security of confidential information. In addition, uncontradicted expert testimony directed specifically toward the State's system for processing and maintaining the triplicate prescription data demonstrated serious deficiencies in security.

It is submitted that this potential for abuse of the information collected coupled with the total lack of a rationale for the collection requires affirmance of the judgment of the Court below.

4. All plaintiffs clearly have standing to sue. The physician plaintiffs' freedom to practice medicine based solely on medical considerations is undermined by the effect on the

patient when he learns of the filing requirement, *Doe* v. *Bolton,* 410 U.S. 179, 199 (1973). The physician, also, is the one against whom the license revocation sanctions of Article 33 operate, *Doe* v. *Bolton, supra, at* 188-9. The patient plaintiffs' right of privacy is infringed by the required disclosure of intimate information to the State. Moreover, every plaintiff in the case (or such plaintiff's child) has been prescribed Schedule II drugs and thus is directly affected by the Act, *Roe* v. *Wade*, 410 U.S. 113, 123-125 (1973). Finally, the plaintiff physician organizations have standing to protect the rights of their members to practice medicine according to the highest medical standards, *NAACP* v. *Alabama,* 357 U.S. 449, 459 (1958).

POINT I

The Challenged Provisions Invade the Constitutional Right of Privacy.

A. The Nature of the Right.

In *Roe* v. *Wade,* 410 U.S. 113 (1973), this Court held that the right of privacy is "founded in the Fourteenth Amendment's concept of personal liberty and restrictions upon state action" (p. 153) and described its genesis and varying contexts as follows (pp. 152-3):

> "The Constitution does not explicitly mention any right of privacy. In a line of decisions, however, going back perhaps as far as *Union Pacific R. Co.* v. *Botsford,* 141 U.S. 250, 251 (1891), the Court has recognized that a right of personal privacy, or a guarantee of certain areas or zones of privacy, does exist under the Constitution. In varying contexts, the Court or individual Justices have, indeed, found at least the roots of that right in the First Amendment, *Stanley* v. *Georgia,* 394 U.S. 557, 564 (1969); in

the Fourth and Fifth Amendments, *Terry* v. *Ohio,* 392 U.S. 1, 8-9 (1968), *Katz* v. *United States,* 389 U.S. 347, 350 (1967), *Boyd* v. *United States,* 116 U.S. 616 (1886), see *Olmstead* v. *United States,* 277 U.S. 438, 478 (1928) (Brandeis, J., dissenting); in the penumbras of the Bill of Rights, *Griswold* v. *Connecticut,* 381 U.S., at 484-485; in the Ninth Amendment, *id.,* at 486 (Goldberg, J., concurring); or in the concept of liberty guaranteed by the first section of the Fourteenth Amendment, see *Meyer* v. *Nebraska,* 262 U.S. 390, 399 (1923). These decisions make it clear that only personal rights that can be deemed 'fundamental' or 'implicit in the concept of ordered liberty,' *Palko* v. *Connecticut,* 302 U.S. 319, 325 (1937), are included in this guarantee of personal privacy. They also make it clear that the right has some extension to activities relating to marriage, *Loving* v. *Virginia,* 388 U.S. 1, 12 (1967); procreation, *Skinner* v. *Oklahoma,* 316 U.S. 535, 541-542 (1942); contraception, *Eisenstadt* v. *Baird,* 405 U.S. at 453-454; *id.,* at 460, 463-465 (White, J., concurring in result); family relationships, *Prince* v. *Massachusetts,* 321 U.S. 158, 166 (1944); and child rearing and education, *Pierce* v. *Society of Sisters,* 268 U.S. 510, 535 (1925), *Meyer* v. *Nebraska, supra.*"

And in *California Bankers Assn.* v. *Shultz,* 416 U.S. 21 (1974), this Court carefully delineated the limitations on governmental intrusion into the zone of privacy. In *Shultz,* several individual bank customers (the "depositor plaintiffs"), banks (the "bank plaintiffs") and others contended that the delegation to the Secretary of the Treasury under the Bank Secrecy Act of broad authority to require reports of domestic monetary transactions from the financial institutions and parties involved was an unconstitutional invasion of privacy. Noting that despite the broad authority granted to the Secretary of the Treasury, the implementing regulations thereunder required only that the financial institution file a report on each domestic transaction in currency of more than $10,000 (31 C.F.R. §103.22), this Court held that the Act, as implemented by the regulations did not unconstitutionally invade the bank plaintiffs' privacy (416 U.S. at 63-7). The Court did not reach the question whether the depositor plaintiffs' privacy had been unconstitutionally infringed because there had been "no allegation by any of the individual depositors that they were engaged in the type of $10,000 domestic currency transaction which would necessitate that their bank report it to the government" (416 U.S. at 68).

The concurring opinion of Mr. Justice Powell, with whom Mr. Justice Blackmun joined, made it clear that a majority of this Court (the two concurring and three dissenting justices*) would not have sanctioned the automatic produc-

* Justices Douglas and Marshall dissented in *Shultz* on the grounds, *inter alia,* that the domestic reporting provisions of the Bank Secrecy Act, even as narrowed by the regulations, constituted an invasion of privacy (see Douglas, J. at 416 U.S. at 87-91 and Marshall, J. at 93-99). Although concurring with part of Justice Douglas' dissent, Justice Brennan based his dissent on the contention that the Act constituted an impermissible delegation of authority to the Secretary of the Treasury. He did not concur with the portion of Justice Douglas' opinion cited above (which relates to the reporting requirements of the Bank Secrecy Act) because, in light of his views on delegation, he could "see no need to address the independent constitutional objections the plaintiffs below attempt to raise" (416 U.S. at 91). However, Justice Brennan did concur with the portions of Justice Douglas' opinion holding that the record keeping requirements also violated the constitutional right of privacy (Douglas, J. at 416 U.S. at 79-86). Also, Justice Brennan found that "the reporting provisions are inseparable from—and in some cases considerably broader than—the record keeping requirements." Accordingly, we submit that it is fairly inferable that, at a minimum, Justice Brennan agreed with the concurring Justices that reporting requirements exceeding those embodied in the regulations promulgated under the Bank Secrecy Act would pose substantial and difficult constitutional questions.

In *Burrows* v. *Superior Court of San Bernadino County,* 13 Cal. 3d 238, 246, 529 P.2d 590, 595, 118 Cal. Reptr. 166, 172 (1974), the California Supreme Court also concluded that the true meaning of *Shultz* was that this Court will not uphold massive reporting requirements such as authorized but not implemented under the Bank Secrecy Act.

tion of large volumes of personal records without a summons or subpoena and without any showing of particularized need therefor. The concurring opinion stated (416 U.S. at 78-9):

> "The Act confers broad authority on the Secretary to require reports of domestic monetary transactions from the financial institutions and parties involved. 31 U.S.C. §§1081 and 1082. The implementing regulations, however, require only that the financial institution 'file a report on each deposit, withdrawal, exchange of currency or other payment or transfer, by, through, or to such financial institution, which involves a *transaction in currency of more than $10,000.*' 31 CFR §103.22 (italics added). As the Court properly recognizes, we must analyze plaintiffs' contentions in the context of the Act as narrowed by the regulations. *Ante,* at 64. From this perspective, I agree that the regulations do not constitute an impermissible infringement of any constitutional right.
>
> "A significant extension of the regulations' reporting requirements, however, would pose substantial and difficult constitutional questions for me. *In their full reach, the reports apparently authorized by the open-ended language of the Act touch upon intimate areas of an individual's personal affairs.* Financial transactions can reveal much about a person's activities, associations, and beliefs. *At some point, governmental intrusion upon these areas would implicate legitimate expectations of privacy. Moreover, the potential for abuse is particularly acute where, as here, the legislative scheme permits access to this information without invocation of the judicial process.* In such instances, the important responsibility for balancing societal and individual interests is left to unreviewed executive discretion, rather than the scrutiny of a neutral magistrate. *United States* v. *U.S. District Court,* 407 U.S. 297, 316-317 (1972). As the issues are presently framed, however, I am in accord with the Court's disposition of the matter." (Emphasis in second quoted paragraph added.)

See also the dissenting opinions of Justices Douglas, Brennan and Marshall (416 U.S. at 79-99).

Thus, a majority of this Court has indicated that a broad requirement of production of documents that "touch upon intimate areas of an individual's personal affairs" pursuant to a legislative scheme "which permits access to this information without invocation of the judicial process" would unconstitutionally invade the individual's privacy.

Recent decisions cited by the State, *Fisher* v. *United States*——U.S.——, 96 S.Ct. 1569 (1976), and *United States* v. *Miller,*——U.S.——, 96 S.Ct. 1619 (1976) (Appellant's Br., p. 20) do not, we submit, affect the foregoing conclusion. *Fisher* upheld a subpoena requiring production of specific records of a designated taxpayer in connection with an investigation by the Internal Revenue service. *Miller* upheld a subpoena of bank records relating to one individual who was the subject of a criminal investigation. Thus, *Fisher* and *Miller* present a striking contrast to the present statute: (1) no massive production was required, merely records relating to the activities of a particular individual under investigation; (2) the documents were not "intimate" in the same sense as documents relating to treatment of an individual's health problems; and (3) in each case, the propriety of the demand was subject to review by the courts.

B. The Invasion of Privacy By the Challenged Provisions.

This Court has held that the right of privacy exists wherever an individual may harbor a reasonable expectation of privacy. For example, in *Terry* v. *Ohio,* 392 U.S.

1 (1968), the Court, while upholding Ohio's stop and frisk law, stated (392 U.S. at 9):

> "We have recently held that 'the Fourth Amendment protects people, not places,' *Katz* v. *United States,* 389 U.S. 347, 351 (1967), and *wherever an individual may harbor a reasonable 'expectation of privacy,' id.,* at 361 (Mr. Justice Harlan, concurring), *he is entitled to be free from unreasonable governmental intrusion.* Of course, the specific content and incidents of this right must be shaped by the context in which it is asserted. For 'what the Constitution forbids . . . not all searches and seizures, but unreasonable searches and seizures.' *Elkins* v. *United States,* 364 U.S. 206, 222 (1960). Unquestionably petitioner was entitled to the protection of the Fourth Amendment as he walked down the street in Cleveland." (Emphasis supplied.)

We submit that where, as here, the statute calls for intimate information pursuant to a statutory scheme which does not allow for invocation of the judicial process, legitimate expectations of privacy are plainly violated.

1. The Statute Sanctions Invasion Into "Intimate Areas of an Individual's Personal Affairs."

In reversing the order of dismissal of the District Court herein and directing that a three-judge court be convened, Judge Friendly, speaking for the Second Circuit, highlighted the intimate nature of the area involved herein (480 F.2d at 108, n. 7; 51a):

> "While the State correctly points out that the prescription form does not require a description of the illness, plaintiffs counter that, at least for some of the drugs in Schedule II, many members of the public know the ailments for which such drugs are commonly prescribed. To take perhaps the most obvious example, most informed people would associate large dosages of Demerol with an ailment causing serious pain. It is immaterial that the ailment usually is not one that should arouse any emotion toward the victim save sympathy; most people simply do not want their ailments to be generally known."

At the trial of this action, several patients indicated that the prospect of having their illnesses "generally known" by having them on file at a centralized state agency caused them acute discomfort and embarrassment. A post-operative cancer patient receiving Percodan to relieve his pain, first tried non-Schedule II drugs as substitutes (196a) and when they did not yield satisfactory results, he obtained the required medicine in New Jersey where the information would not be put on a state-run computer (197a). Another plaintiff, disregarding her doctor's advice, would not permit her son, who suffered from hyperkinesis, to continue receiving prescriptions for the Schedule II drug Ritalin after she learned that the prescription therefor, containing his identity, would be placed on the State's computer in Albany (170a-172a). Similarly, it hardly seems necessary to suggest that patients who suffer from ocular gyro-crises (involuntary upward rolling of the eyes) (137a, 158a-159a) are distraught at the prospect of the centralized and easy access to information about their treatment. And all the other patient plaintiffs made it unmistakably clear that they "simply do not want" information describing prescriptions which they or their children are required to take for entirely legitimate medical reasons to be filed with and computerized by the State (114a-137a, 137a-139a, 140-145a, 211a-212a).*

* For example, Mr. Moe testified that several physicians had advised him and his wife that their son "would have to take something like Ritalin for him to have any hope of having a normal childhood and learning" (116a) and his fear that "by the time my boy is an active citizen, there will be a long file on him in a narcotics or dangerous drug context, in which somebody can get a printout and use it, once they have it, for whatever they use it for" (123a).

The result of the State's intrusion into the privacy of the doctor-patient relationship is poignantly demonstrated by the experiences of various doctors who testified in the present case. Plaintiff Matthew Brody, a psychiatrist and neurologist, found that all his patients who received Schedule II drugs were shocked and hurt when they learned of the filing requirements (154a). And Dr. Brody had to terminate treatment of patients suffering from schizo-affective disorders by use of Schedule II drugs (158a) because, even though such drugs were medically indicated and highly beneficial for such patients, the suspicion created by the filing requirement endangered the physician-patient relationship (154a-155a, 168a-169a). Other physicians found that several of their patients refused to continue using Schedule II drugs when they learned of the filing requirements (180a-181a, 186a-187a, 213a-214a). For example, Dr. Fishman, a witness, testified that the son of an elderly patient of his insisted that his mother no longer receive a Schedule II drug because of the filing requirement and that, thereafter, the patient had an immediate and prompt weight gain, her blood pressure went back up and she became bed-ridden (177a-180a). And Dr. Lustig, a plaintiff in the *Patient* action, testified that he refused to prescribe Schedule II drugs, even to relieve pain after surgery, because of the filing requirement (204a-208a).

Such physician and patient reactions are not unique. Dr. Jerry Rosenberg, a highly qualified psychologist and author who has studied the impact on the individual resulting from the accumulation of personal data about such individual (234a-240a), testified to reactions that would result from the accumulation of this data, including increased incidence of conforming behavior, withdrawal, lowered productivity, fear of or antagonism toward government and even, under some circumstances, physical symptoms (240a-252a). He concluded that there is some negative psychological impact on every person who knows that a triplicate prescription concerning drugs that he or his family is taking is being filed in Albany (252a-253a) and that such negative impact is likely to be greater where it occurs in a stressful situation, such as a sick patient seeking advice from a physician (254a-255a).

In addition to the "individual's interest in keeping to himself the existence of his physical ailments and his doctor's prescriptions for them" noted by Judge Friendly (*Roe* v. *Ingraham, supra,* at 108; 51a), the foregoing evidence demonstrates the direct infringement of two other aspects of the right of privacy: the patient's "right to receive medical care in accordance with her licensed physician's best judgment" (*Doe* v. *Bolton, supra,* at 197) and "the physician's right to practice" (*id.*, at 199).

The uncontradicted evidence herein reveals numerous instances where physicans did not prescribe medically indicated medications for their patients solely because of non-medical considerations such as the effect of knowledge of the filing requirement on the physican-patient relationship (154a-155a, 158a, 177a-180a, 180a-181a, 186a-187a, 204a-208a, 213a-214a). Indeed, the legislative history shows that a principal reason for requiring the filing of triplicate prescriptions containing patient names was the frank intention of the statutory draftsman to discourage alleged "over-prescribing" of Schedule II drugs (Ex. 32, p. 21; Ex. 33, p. 2) even while recognizing their medical utility (Ex. 32, pp. 13, 61, 81-82). And the State urges to this Court that the statute thereby achieves a "prophylactic effect" against "[b]ogus patients and unscrupulous doctors." As shown below, the evidence demonstrates no effect whatever on "bogus patients" (see *infra,* pp. 42-46).

And as to "unscrupulous doctors", we submit that disclosure of patients' names* is not a proper means to discourage prescription of the drugs. As this Court stated in *Doe* v. *Bolton* 410 U.S. 179 (1973) when it invalidated a Georgia statute requiring two-doctor concurrence prior to an abortion (*supra,* at 199):

> "If a physician is licensed by the State, he is recognized by the State as capable of exercising acceptable clinical judgment. If he fails in this, professional censure or deprivation of his license are available remedies. Required acquiescence by co-practitioners has no rational connection with a patient's needs and unduly infringes on the physician's right to practice."

Justice Douglas made the same point in his concurring opinion (410 U.S. at 219):

> "The State licenses a physician. If he is derelict or faithless, the procedures available to punish him or to deprive him of his license are well known. He is entitled to procedural due process before professional disciplinary sanctions may be imposed. See *In re Ruffalo,* 390 U.S. 544. Crucial here, however, is state-imposed control over the medical decision whether pregenancy should be interrupted. The good-faith decision of the patient's chosen physician is overridden and the final decision passed on to others in whose selection, the patient has no part. This is a total destruction of the right of privacy betwen physician and patient and the intimacy of relation which that entails."

Similarly, in this case, the legislative intention to discourage prescription of certain drugs has no rational con-

* The statute provides for (and we have no objection to) disclosure of physicians' names and the amounts of Schedule II drugs they prescribe (§ 3332(2)), which, in any event, appears to be a far more effective and direct way to apprehend physicians who overprescribe (see also pp. 45-6, *infra*).

nection with a patient's needs. Disclosure of the patient's identity entails "destruction of the right of privacy between physician and patient." Legislation requiring the filing of each and every prescription for Schedule II drugs unduly infringes the patient's right to receive treatment and the physician's right to practice. If a physician is derelict or faithless in prescribing drugs, the procedures available to punish him or to deprive him of his license are well known. This Court held in both the *Doe* and *Roe* cases that remedies of professional censure or deprivation of the physician's license are fully adequate to situations where a physician abuses his trust.

2. *The Challenged Legislative Scheme Does Not Allow for "Invocation of the Judicial Process."*

While an individual has no recognizable right of privacy merely because a government agency by summons or subpoena requires the production of personal records, we submit that the right to privacy does come into play where the State requires the automatic production of such records relating to a large number of persons without summons or subpoena and without any showing of need for the patients' identities. *California Bankers Assn.* v. *Shultz, supra; United States* v. *Stanack Sales Co.,* 387 F.2d 849 (3d Cir. 1968).

In *California Bankers Assn., supra,* three dissenting and two concurring justices indicated that regulations requiring reports by financial institutions and persons participating in domestic financial transactions of all transactions in currency or any monetary instruments—large or small—by all persons engaging in such transactions would violate the constitutional right of privacy, notwithstanding the absence of any privilege for communications between banks and their customers, because bank customers have a reasonable expectation of privacy concerning details of their financial affairs (see, *supra,* pp. 16-19).

Justice Harlan stated his understanding in *Katz* v. *United States*, 389 U.S. 347, 361 (1967), concerning what is meant by privacy as follows:

> "My understanding of the rule . . . is that there is a twofold requirement, first that a person have exhibited an actual (subjective) expectation of privacy, and second, that the expectation be one that society is prepared to recognize as 'reasonable'."

Clearly, a patient has more reason to expect privacy concerning details of his health than does a bank customer with respect to details of his financial transactions (*California Bankers Assn.* v. *Schultz, supra*) or a drug packager with respect to the records of his business (*United States* v. *Stanack Sales, supra*). The necessity for protection against dissemination of computerized information has been recognized by Congress (see e.g., The Privacy Act of 1974, 5 U.S.C. § 552a (1974)). The privilege for physician-patient communications is old and well established (see 8 Wigmore on Evidence § 2380 et seq. [McNaughton Rev. 1961]) and protects the peculiarly confidential nature of the relationship upon which the present Act encroaches.

As Justice Douglas stated in concurrence in *Roe* v. *Wade* and *Doe* v. *Bolton* (410 U.S. at 219): "The right of privacy has no more conspicuous place than in the physician-patient relationship, unless it be in the priest-penitent relation."

Plaintiffs herein do not contend that the retention by a pharmacist of a copy of a prescription for a statutory period such as five years is an unreasonable diminution of their expectation of privacy. Plaintiffs neither concede nor reach the question whether prior New York State law (which apparently permitted a state investigator to obtain access to such documents without a warrant) was constitutional.*

* As indicated by *California Bankers Assn.* v. *Shultz, supra*, *Camara* v. *Municipal Court*, 387 U.S. 523 (1967), *See* v. *City of Seattle*, 387 U..S 541 (1967), *Collonade Catering Corp.* v. *United States*, 397 U.S. 72 (1970), and *United States* v. *Bissell*, 406 U.S. 311 (1972), this is a substantial and difficult question.

But we do submit that there is a world of difference between permitting an inspector access to records in the course of an investigation and requiring all pharmacies and doctors to turn over all such information *automatically* to the State. The old system was, by its very nature, a guarantee of reasonable privacy. The automatic collection of vast volumes of personal data by a centralized state agency obviously creates a far greater likelihood of invasion of privacy.

Appellant has characterized the three judge court's legitimate concern that constitutional rights not be compromised on the grounds of administrative efficiency (J.S. 12a; 403 F. Supp. at 937-938) as "judicial Luddism" (Appellant's Br., p. 30). Yet Courts have protected constitutional rights, where they were found to apply, despite the clear prospect of increased administrative inconvenience and burden. See e.g., *Morrissey* v. *Brewer*, 408 U.S. 471 (1972); *Argersinger* v. *Hamlin*, 407 U.S. 25 (1972); *Id.*, at 41-44 (Burger, C.J. concurring); *Goldberg* v. *Kelly*, 397 U.S. 254 (1970); *Population Services International* v. *Wilson*, 398 F. Supp. 321, 335 (S.D.N.Y. 1975) *prob. juris. noted sub nom., Carey* v. *Population Services International*, 44 L.W. 3162 (Sept. 20, 1975); *Almenares* v. *Wyman*, 334 F. Supp. 512 (S.D.N.Y.), *aff'd as modified* 453 F.2d 1075 (2d Cir. 1971), cert. denied, 405 U.S. 944 (1972).

The Act presently under consideration, unlike the Bank Secrecy Act, is "self-executing" (cf. 416 U.S. at 64). Not even a request by a state agent is needed. Unlike *Shultz*, where the Act became effective only after the Secretary of the Treasury promulgated regulations, no regulations to implement the reporting requirements of Article 33 need be promulgated by the Commissioner of Health. Also, in *Shultz*, this Court emphasized that "the legislative history of the Act clearly indicates that records which it authorized the Secretary to require [banks to keep] were to be available only by normal legal process. . . ." (416 U.S. at 54.) In sharp contrast, under the Act here challenged (1) there is no requirement that an administrative summons, sub-

poena or warrant be issued and (2) the records turned over need not be claimed to be relevant and material to a specific matter then under inquiry (3) the records inspected relate to a large number of persons and (4) the records all relate to the most intimate personal affairs.

By explicitly providing that huge volumes of personal records be turned over *automatically* by every doctor and pharmacist in the State who prescribes or dispenses Schedule II drugs, we submit that the Act clearly infringes the constitutional right of privacy.

POINT II

Because the Right of Privacy Is Fundamental, a "Compelling State Interest" Should Be Shown Before a State Invasion of Privacy Is Permitted.

This Court has consistently recognized that the right of privacy, "the most comprehensive of rights and the right most valued by civilized men" (*Olmstead* v. *United States,* 277 U.S. 438, 478 [1928] Brandeis, J. dissenting), is a "fundamental [right] implicit in the concept of ordered liberty" (*Roe* v. *Wade, supra,* at 152 quoting *Palko* v. *Connecticut,* 302 U.S. 319, 375 (1937)). Accord, *Paul* v. *Davis,* —— U.S. ——, 96 S.Ct., 1155, 1166 (1976). A heavy burden should therefore be placed on a state seeking to justify statutory intrusion into constitutionally protected zones of privacy. This burden has most frequently been articulated as a requirement that the statute in question be justified by a "compelling state interest."*

* The State argues at one point (Appellant's Br., p. 12) for the existence of "an almost absolute [state] right to control the sale, prescription and use of dangerous drugs" citing *Whipple* v. *Martinson,* 256 U.S. 41 (1921) and *Robinson* v. *California,* 370 U.S. 660 (1962). However the *Robinson* case itself makes clear that no such "absolute" right exists. In that case, this Court held that California's attempt to control the problem of narcotics addiction by making such addiction a criminal offense violated the Eighth and Fourteenth Amendments to the Constitution. See also *United States* v. *Rivera-Marquez,* 519 F.2d 1227, 1228-1229 (9th Cir.) cert. denied, —— U.S. ——, 96 S.Ct. 369 (1975).

Thus in *Roe* v. *Wade, supra,* this Court in discussing the burden on a state seeking to justify a statute invading the right to privacy stated (410 U.S. at 155-6):

> "Where certain 'fundamental rights' are involved, the Court has held that regulation limiting these rights may be justified only by a 'compelling state interest,' *Kramer* v. *Union Free School District,* 395 U.S. 621, 627 (1969); *Shapiro* v. *Thompson,* 394 U.S. 618, 634 (1969); *Sherbert* v. *Verner,* 374 U.S. 398, 406 (1963), and that legislative enactments must be narrowly drawn to express only the legitimate state interests at stake. *Griswold* v. *Connecticut,* 381 U.S. at 485; *Aptheker* v. *Secretary of State,* 378 U.S. 500, 508 (1964); *Cantwell* v. *Connecticut,* 310 U.S. 296, 307-308 (1940); see *Eisenstadt* v. *Baird,* 405 U.S. at 460, 463-464 (White, J., concurring in result).
>
> "In the recent abortion cases, cited above, courts have recognized these principles. Those striking down state laws have generally scrutinized the State's interests in protecting health and potential life, and have concluded that neither interest justified broad limitations on the reasons for which a physican and his pregnant patient might decide that she should have an abortion in the early stages of pregnancy. Courts sustaining state laws have held that the State's determinations to protect health or prenatal life are dominant and constitutionally justifiable."

See also *Buckley* v. *Valeo,*——U.S.——, 96 S.Ct. 612, 656-7 (1976) (describing the standard to be applied to statutes invading the right of privacy as one of "strict . . . scrutiny").

Parallel to the requirement that invasion of a constitutionally protected zone of privacy must be in the service of a fundamental state interest is the further requirement that the compelling state interest allegedly served must be grounded in fact and must not be merely conjecture on the part of state officials.

Thus in *Doe* v. *Bolton, supra,* this Court in discussing a Georgia statute requiring that abortions be performed only in an appropriately accredited hospital stated (410 U.S. at 195):

> "Appellants and various *amici* have presented us with a mass of data purporting to demonstrate that some facilities other than hospitals are entirely adequate to perform abortions if they possess these qualifications. The State, on the other hand, has not presented persuasive data to show that only hospitals meet its acknowledged interest in insuring the quality of the operation and the full protection of the patient. We feel compelled to agree with appellants that the State must show more than it has in order to prove that only the full resources of a licensed hospital, rather than those of some other appropriately licensed institution, satisfy these health interests."

Similarly in the instant case, the State's alleged interest in having patient names on centrally filed prescriptions is unsupported by any data, being mere conjecture which was contradicted by the evidence adduced at trial (Point IIIA, *infra*).

Justice Stewart noted in his concurring opinion in *Roe* v. *Wade, supra,* that the fundamental nature of the right to privacy has not been limited solely to matters of marriage and family life but has been held to include the right to send a child to private school and the right to teach a foreign language. He stated (410 U.S. at 169-170):

> "As Mr. Justice Harlan once wrote: '[T]he full scope of the liberty guaranteed by the Due Process Clause cannot be found in or limited by the precise terms of the specific guarantees elsewhere provided in the Constitution. This "liberty" is not a series of isolated points pricked out in terms of the taking of property; the freedom of speech, press, and religion; the right to keep and bear arms; the freedom from

> unreasonable searches and seizures; and so on. It is a rational continuum which, broadly speaking, includes a freedom from all substantial arbitrary impositions and purposeless restraints . . . and which also recognizes, what a reasonable and sensitive judgement must, that certain interests require particularly careful scrutiny of the state needs asserted to justify their abridgment.' *Poe* v. *Ullman,* 367 U.S. 497, 543 (opinion dissenting from dismissal of appeal) (citations omitted). In the words of Mr. Justice Frankfurter 'Great concepts like . . . "liberty" . . . were purposely left to gather meaning from experience. For they relate to the whole domain of social and economic fact, and the statesmen who founded this Nation knew too well that only a stagnant society remains unchanged.' *National Mutual Ins. Co.* v. *Tidewater Transfer Co.,* 337 U.S. 582, 646 (dissenting opinion).
>
> "Several decisions of this Court make clear that freedom of personal choice in matters of marriage and family life is one of the liberties protected by the Due Process Clause of the Fourteenth Amendment. *Loving* v. *Virginia,* 388 U.S. 1, 12; *Griswold* v. *Connecticut, supra; Pierce* v. *Society of Sisters, supra; Meyer* v. *Nebraska, supra.* See also *Prince* v. *Massachusetts,* 321 U.S. 158, 166; *Skinner* v. *Oklahoma,* 316 U.S. 535, 541. As recently as last Term, in *Eisenstadt* v. *Baird,* 405 U.S. 438, 453 we recognized 'the right of the *individual,* married or single, to be free from unwarranted government intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child.' That right necessarily includes the right of a woman to decide whether or not to terminate her pregnancy. 'Certainly the interests of a woman in giving of her physical and emotional self during pregnancy and the interests that will be affected throughout her life by the birth and raising of a child are of a far greater degree of significance and personal intimacy than the right to send a child to private school protected in *Pierce* v. *Society of Sisters,* 268 U.S. 510 (1925), or

> the right to teach a foreign language protected in *Meyer* v. *Nebraska,* 262 U.S. 390 (1923)'. *Abele* v. *Markle,* 351 F. Supp. 224, 227 (D.Conn. 1972)."

See also *Paul* v. *Davis,*——U.S.——, 96 S.Ct. 1155, 1166 (1976).

Judge Friendly, speaking for the Second Circuit in this case, after quoting a part of the foregoing passage, further observed (480 F.2d at 108; 51a):

> "Should the constitutionally protected zone of privacy be extended beyond the area already recognized, the individual's interest in keeping to himself the existence of his physical ailments and his doctor's prescriptions for them would lie rather close in the continuum."

We urge that this Court should recognize the threat to constitutional rights posed by personal data systems and the nature of the injury inherent in the abusive character of such systems. As one commentator has stated:

> "The Court should re-focus its conception of the fundamental right of personal privacy in light of twentieth century technology and the executive-dominated federal government. Privacy, interests in thought, self, reputation, and psychic security did not need express protection in the past because no real threat of invasion appeared to exist. Today the threat is both real and pervasive, and the Court must recognize the right 'implicit in the concept of ordered liberty.'" Note, *Right of Privacy,* 69 Nw. U. L. Rev. 263, 295 (1974).

See also S. Rep. No. 93-1183, 93rd Cong., 2d Sess. p. 4 (1974) (remarks of Senator Ervin). Well publicized Watergate-allied events as well as specific instances of abuses in New York State discussed below (*infra,* pp. 54-60) make plain the need to extend constitutional protection

to parties whose privacy has already been invaded by different forms of data collection. See also *Menard* v. *Mitchell,* 430 F.2d 486 (D.C. Cir. 1970) and on remand, 328 F. Supp. 718 (D.D.C. 1971); *Eddy* v. *Moore,* 5 Wash. App. 334, 487 P. 2d 211 (1971); *Davidson* v. *Dill,* 503 P. 2d 157 (Colo. S.C. 1972).

The development of modern methods of computerization of records, affording state investigators instant access to enormous volumes of personal information, poses a new and greater threat to privacy with which the Courts must keep pace. As the Supreme Court of California observed in *Burrows* v. *Superior Court of San Bernardino County,* 13 Cal. 3d 238, 246, 529 P. 2d 590, 593, 118 Cal. Reptr. 166, 172 (1974):

> "Cases are legion that condemn violent searches and invasions of an individual's right to the privacy of his dwelling. The imposition upon privacy, although perhaps not so dramatic, may be equally devastating when other methods are employed. Development of photocopying machines, electronic computers and other sophisticated instruments have accelerated the ability of government to intrude into areas which a person normally chooses to exclude from prying eyes and inquisitive minds. Consequently judicial interpretations of the reach of the constitutional protection of individual privacy must keep pace with the perils created by these new devices.[4]"

"4. In 1890, Samuel Warren and Louis Brandeis, in their celebrated article, The Right to Privacy (4 Harv.L. Rev. 193, 195) foresaw this problem. They wrote: 'Recent inventions and business methods call attention to the next step which must be taken for the protection of the person, and for securing to the individual what Judge Cooley calls the right "to be let alone." Instantaneous photographs and newspaper enterprise have invaded the sacred precincts of private and domestic life; and numerous mechanical devices threaten to make good the prediction that 'what is whispered in the closet shall be proclaimed from the house-tops.' (Fn. omitted.)"

See also, *Drake* v. *Covington County Bd. of Educ.*, 371 F. Supp. 974, 979 (M.D. Ala. 1974) (Absent any compelling state interest, the cancellation of an unmarried, pregnant teacher's employment contract for immorality violated the teacher's right of privacy, when the board of education based its action on evidence obtained from the teacher's physician); *Merriken* v. *Cressman,* 364 F. Supp. 913 (E.D. Pa. 1973) (A preventive drug abuse program which was designed to aid a school district in identifying potential drug abusers through the use of "family-life" oriented questionnaires was held to violate students' and parents' rights to privacy); *In re Lifschutz,* 85 Cal. Rptr. 829, 497 P. 2d 557, 567-568 (Cal. Sup. Ct. 1970) (Under certain circumstances, confidentiality of a psychotherapeutic session would fall within the zone of constitutionally protected privacy); *Town of Huntington* v. *N.Y. State Drug Abuse Control Comm.,* 84 Misc. 2d 138, 145-148, 373 N.Y.S. 2d 728, 736-739 (Sup. Ct. Nas. Co. 1975); Boyer, *Computerized Medical Records and the Right to Privacy: The Emerging Federal Response,* 25 Buffalo L. Rev. 37, 87-89 (1975).

We urge that in the instant case this Court recognize the threat to the individual's privacy created by the enormously enhanced capabilities for a storage and retrieval of information created by the computer. When *Olmstead* v. *United States,* 277 U.S. 438 (1928) was decided, this Court could not accept that an invasion of privacy had taken place by wiretapping because no physical thing had been taken and no physical space had been penetrated. However, subsequently in *Katz* v. *United States,* 389 U.S. 347, 352 (1967), this Court rejected ancient requirements of trespass and held that the defendant therein, as a user of a pay telephone, had a right to expect "that the words he uttered into the mouthpiece . . . [would] not be broadcast to the world." Similarly, the Court should recognize that the concept of ordered liberty in a modern society implies

a right of privacy to be protected against government collection and storage of massive volumes of personal data of the type involved in this case. See *Roe* v. *Ingraham,* 364 F. Supp. at 543; J. S. 12a; Note, *Right of Privacy,* 69 Nw. U. L. Rev 263, 292-293 (1974).

We submit that the privacy interests involved in the instant case are fundamental to the concept of ordered liberty and, accordingly, that the "compelling state interest" test should be applied rather than the "rational basis" test advocated by the appellant (brief at 21-26). We know of no authority for the application of "middle level security" to the instant statute except in so far as the concept of "middle level scrutiny" is referrable to the requirement discussed above that the compelling state interest allegedly served "have substantial basis in actuality, not merely in conjecture." (Gunther, *Foreword: In Search of Evolving Doctrine on a Changing Court: A Model for a Newer Equal Protection,* 86 Harv. L. Rev. 1, 21 (1972)). See generally Note, *The Right to Privacy,* 50 N.Y.U. L. Rev. 1149 (1976).

The State raises the spectre of *Lochner* v. *New York,* 198 U.S. 45 (1905), arguing that affirmance of the decision of the court below "would be a revival of substantive due process" (Appellant's Br. at 10). The argument has been fully answered in this Court, *Roe* v. *Wade, supra,* at 167 (Stewart, J. concurring) and at 212 n. 4 (Douglas, J. concurring). And, as Professor Gunther has pointed out, relying on Justice Holmes' dissent in *Lochner,* "the primary evil of the discredited [*Lochner*] doctrine was the dogmatic judicial intervention regarding ends, not means." Gunther, *supra,* at 42. Appellees concede that control of dangerous drugs is a legitimate end of state legislation. However, a state may not massively intrude into the private lives of individuals in the name of drug control, where no relationship between such intrusions and the concededly legitimate state goal can be demonstrated.

The state further speculates that affirmance may "jeopardize" other statutes. (Appellant's Br., pp. 17, 38-39.) It is submitted that affirmance would no more jeopardize these statutes than have the opinions of this Court in the *Roe* and *Doe* cases, *supra, Griswold* v. *Connecticut,* 381 U.S. 479 (1965) and *Eisenstadt* v. *Baird,* 405 U.S. 438 (1972). It may well be that some aspects of the physician-patient relationship are constitutionally protected, while others are not. See, e.g. *In re Lifschutz, supra.* Thus the reasonableness of the expectation of privacy in reporting a gunshot wound to a physician may be quite different from the reasonableness of the expectation of a patient receiving a prescription drug for legitimate medical reasons. See also Boyer, *supra,* at 87-88 (1975).

This Court is not faced with the cases hypothesized by the state. We submit that for the great majority of people, records of the type involved in this case are the most sensitive kinds of personal information that will ever be collected* and that before the government is permitted to store such intimate data as to citizens who have done nothing wrong except to fall ill, it should be required to demonstrate a compelling state interest.

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* The three-judge court herein stated:

> "An individual's physicial ills and disabilities, the medication he takes, the frequency of his medical consultation are among the most sensitive of personal and psychological sensibilities. One does not normally expect to be required to have to reveal to a government source, at least in our society, these facets of one's life. Indeed, generally one is wont to feel that this is nobody's business but his doctor's and his pharmacist's." (J. S. 10a; 403 F. Supp. at 937).

POINT III

Under Either the Compelling State Interest Test or the Rational Relationship Test, the Statute's Consitutionality Cannot Be Sustained.

A. The Absence of Any Need for the Challenged Provisions.

The Court of Appeals herein found that the "most important" justification proffered by the State in support of the centralized filing requirement was that the State needed the names of parties receiving Schedule II drugs to detect four types of abuses. Thus, the Court of Appeals stated (480 F.2d at 108; 52a-53a):

> "New York has advanced powerful arguments in support of the requirement of central filing of prescriptions for Schedule II drugs. The *most important* are that only by such filing, now complemented by the computer's ability to answer appropriate inquiries, can the State readily detect a number of serious abuses—the same patient going from doctor to doctor and thereby obtaining quantities of Schedule II drugs greater than his legitimate medical needs; overprescription by doctors; and the theft or forgery of prescriptions." (Emphasis added.)

The three-judge court, at the time of plaintiffs' motion for a preliminary injunction, held that the issue of need for the patient's name and address on the filed prescription form was the "critical question" of this case and directed plaintiffs to "submit the necessary intensive and detailed analysis of the competing interests of the state and the individual", including specifically a demonstration "that the computerization of names is not necessary for the accomplishment of the state's goals" (364 F.Supp. at 546; 76a).

Not only did plaintiffs submit such an analysis (see *supra,* pp. 6-8 and *infra,* pp. 39-53), but the State withdrew the argument (previously cited to the Court of Appeals as the *raison d'etre* for the challenged provisions) that patients' names are required to detect the four alleged "abuses" cited by the Court of Appeals. Thus, allegations that the patient-identification provisions are needed to detect "over-prescriptions", "thefts", and "forgeries" were not urged to the Court below. The State conceded to the Court below that it did *not* need patients' names to solve any of those problems (see testimony cited, *infra,* at p. 43) and *stipulated* that the only need for patients' names is to counteract the so-called "doctor to doctor" problem alluded to by the Court of Appeals (95a, par. 12).

Appellant's present brief does not cite any evidence whatever of the supposed abuse of "the same patient going from doctor to doctor and thereby obtaining quantities of Schedule II drugs greater than his legitimate medical needs" (480 F.2d at 108; 52a). Instead, appellant resorts to alleged facts solely in his possession and verifiable solely by him.* We submit that such "facts", which are no part of the record of this case, never referred to in response to plaintiffs' discovery requests or testified to by defendant's witnesses or subjected to cross-examination and never cited to the Court below, are entitled to no weight whatever.

As was stated by this Court in *Schley* v. *Pullman Car Co.,* 120 U.S. 575, 578 (1887):

> "[T]he defendant in error states many things [in his brief], which he declares to be 'incontrovertible facts' . . . which are wholly unsustained by anything in the record. . . . The excuse given for this breach of professional propriety is 'the extreme brevity of the record.' . . . The excuse given furnishes no apology whatever for his violation of the terms of the stipulation; much less does it palliate his attempt to influence the decision here, by reference to matters not in the record, and which, he must have known, could not be taken into consideration. It is only necessary to say that the facts, *dehors* the record, which have been improperly introduced into the brief of the counsel for the defendant in error, have not in any degree influenced our determination of the case."

* Among the "facts" in appellant's brief which are totally unsupported by the record are those in note (*) at 9, notes (*) and (***) at 27; note (*) at 29; note (*) at 30; and note (*) at 37.

Accord, *Thomson* v. *Gaskill,* 315 U.S. 442, 446 (1942); *Smith* v. *United States,* 343 F.2d 539, 541 (5th Cir. 1965), *cert. denied* 382 U.S. 861 (1965); *Walters* v. *Chicago and North Western Ry. Corp.,* 216 F.2d 332, 336 (7th Cir. 1954); *Bono* v. *United States,* 113 F.2d 724, 725 (2d Cir. 1940).

Indeed, the principal "justification" proferred by the State is a reference to "45 instances or referrals of over-prescription *and/or* multiple sources (doctor to doctor shopping)" (Appellant's Br., pp. 27-28, fn, emphasis added). Obviously, the word "and/or" conceals the salient facts. It has always been recognized that the patient's name is not necessary to detect over-prescriptions because the practitioner himself sets forth maximum daily dosage on the prescription together with the total quantity prescribed (29a). Consequently over-prescriptions can be ascertained without the patient's name either (a) by dividing the total prescribed by the maximum daily dosage to see whether an amount for more than 30 days has been prescribed or (b) by comparing the amounts prescribed with standard prescriptions. In neither case is the patient's name necessary or even useful. In any event, if an investigation of the particular patient were required, the patient's name could be obtained directly from the doctor or pharmacy, both of which are identified on the prescription (29a).

More important, the uncontradicted record proof is that "doctor to doctor" cases were utterly insignificant prior to 1973 (3 cases reported in 4 years) and have continued to be *de minimis* since institution of the present system (2 case reports, with no convictions or arrests based thereon) (see *supra,* pp. 6-8; *infra,* pp. 43-45).

The plain fact is that there never has been a "doctor to doctor" problem. Notwithstanding defendant's assertion that "much study" was given to this "legislation" (Appellant's Br., p. 46), the entire "legislative history" supporting the existence of a "doctor to doctor" problem consists of one passing reference in the Second Interim Report (Ex. 32, p. 21). No testimony has been cited from the legislative history or elsewhere where the matter was even discussed. No statistics as to the extent of such an alleged problem have ever been adduced. There is, in short, not a scintilla of evidence that such a problem has ever existed.

In support of the foregoing statements, we turn now to a detailed review of the legislative history, the evidence in this case and similar statutes in other states and the federal government, all of which demonstrate the complete absence of any legitimate purpose for the challenged provisions.

1. The Legislative History of Article 33 Provides No Rationale As to a "Need" for Patients' Names.

The purpose of Article 33 was stated by Governor Rockefeller at the time of its enactment on June 8, 1972 to be to "help reduce the diversion of potentially dangerous drugs from legal, medical and research uses into illegal channels" (Governor's Memorandum on approving L. 1972 cc. 878 to 881, 2 McKinney's 1972 Session Laws of N. Y., at p. 3407).

Assemblyman Chester A. Hardt, Chairman of the Temporary State Commission to Evaluate the Drug Laws, made

the same point with respect to triplicate prescriptions. In his memorandum to members of the legislature prior to the bill's enactment, he stated that "the triplicate prescription provision is but one facet of the comprehensive system of control against diversion of lawfully manufactured, distributed, prescribed and dispensed psychoactive drugs. . . ." (Ex. 33, p. 1.)

However, the legislative history shows that no consideration whatever was given to the question whether the patient's name is required on the copy of the triplicate prescription form filed in Albany (See Ex. 31-33).* In the rare instances where the triplicate prescription provisions were discussed (principally the Hardt Memorandum [Ex. 33] and the Second Interim Report [Ex. 32] at pp. 21-22), the discussion consisted of generalized and unsupported claims that they will assist in enforcement of the Act, such as this paragraph from the Second Interim Report (Ex. 32, p. 21):

> "Once, the department has received the copies, it will be able to compile data which will uncover irregularities such as forgeries, fraudulent obtaining of schedule II substances, and thefts of prescription blanks and their misuse by unauthorized persons. The information received by the department will show if a patient has obtained prescriptions by going from doctor to doctor, or if stolen prescriptions are being used. This procedure will also indicate whether there has been an over-prescribing or over-dispensing of Schedule II drugs."

The evidence in this case, as detailed below, shows that such claims are baseless; that over-prescription, over-dispensing of drugs and abuses resulting from thefts and forgeries of prescription blanks can all be detected equally

* It was stipulated that three reports (Ex. 31-33) constitute the entire legislative history of the Act for purposes of this case (81a-82a).

well without computerization of patient's names; and that the sole remaining abuse cited, the obtaining of illicit amounts of drugs by going from "doctor to doctor" is minimal. These facts were not considered by the legislature. Indeed, the legislative history of the challenged provisions reveals that the drafters of the Act never considered *any* of the following questions: whether accomplishment of the foregoing objectives could be achieved equally well without the patient's name; whether the patient's identity is actually required in any instance; and, if so, whether the abuse cited is sufficiently wide-spread to warrant the collection of data on 125,000 patients per month or 1.5 million prescriptions containing patients' names per year.

The answers to these questions (as contained in the evidence in this case) demonstrate the complete absence of any need for patients' names.

2. *The Experience of the Department of Health Demonstrates That There Is No Need for Patients' Names on the Filed Prescriptions.*

Although the Second Interim Report cited numerous "irregularities" which would be "uncovered" by triplicate prescriptions (see Ex. 32, p. 21 quoted *supra*, pp. 39-40), the State conceded that the name on the prescription is of use to the State in only one instance: in detecting cases of persons who have gone "from doctor to doctor" to obtain excessive amounts of a Schedule II drug. Moreover, the patient's name is only of use if, in going from doctor to doctor, the patient uses the same name.* Thus, the State stipulated as follows (95a, par. 12):

* The *Amicus* brief of the State of California confirms that the "doctor to doctor" problem was the only conceivable purpose for the patient identification provisions (Cal. *Amicus* Br., p. 8). Thus, the first hypothetical given therein is that "a patient without using an

(*footnote continued on following page*)

> "The only information from the computer which Dr. Baker contemplates would contain the names of any patients is a print-out of patients who have obtained more than a 30-day supply of a Schedule II drug in a 30-day period. The only reason given by Dr. Baker for the above print-out is that it will assist in the identification and investigation of persons who, *using the same name*, go from doctor to doctor to obtain an illicit supply of Schedule II drugs." (Emphasis added.)

Dr. Arthur G. Baker, Associate Commissioner of the New York State Department of Health and the person charged with over-all responsibility for the triplicate prescription program, so testified in this case (Ex. 37, p. 139):

> "Q. Really we come back to what we said before, and that is the only reason why you have requested that the patient's name be put on the computer is to detect patients who go from doctor to doctor in order to obtain an excessive amount of a particular drug.
>
> A. That's correct."

Dr. Baker also admitted that patients' names on the computer would not assist in detecting forgeries or raised prescriptions or thefts because the patient information on such prescriptions would be incorrect anyway (Ex. 37, pp. 118-21, 126-29).

Nor has there ever been any indication in the Department of Health that the problem of persons going from

(*footnote continued from preceding page*)

alias could go from doctor to doctor to obtain Schedule II drugs" (*id.*). The other hypotheticals suggested—prescriptions to "an addict or habitual user" or to persons "using fictitious names" (*id.*) have no application to this case. The New York statute (§3331(1)) provides that Title IV (which includes the filing requirements at issue herein) does not apply to the prescribing or dispensing of controlled substances to an addict or habitual user. And, as noted above, it has been conceded by the State of New York that computerization of fictitious names is of no aid in enforcement of the statute (see 95a, par. 12 and testimony of Dr. Baker in Ex. 37 at 118-20).

"doctor to doctor" was serious or widespread. On November 15, 1974, the State also stipulated that from January 1, 1969 to May 12, 1974, there had been only four case reports of "doctor to doctor" type violations (95a, par. 12), distributed as follows:

1974	1 case
1973	None
1972	None
1971	1 case
1970	1 case
1969	1 case

Although Defendant's Trial Memorandum stated that Mr. Cannizzaro would testify "that the computer indicates that there are hundreds of persons, using the same name, receiving Schedule II drugs from more than one doctor, i.e., shopping" (Deft's Trial Memo., p. 10), there was in fact no such testimony and no evidence that additional cases of patients going from doctor to doctor were referred to BNC. On the contrary, Cannizzaro testified that he had no knowledge of a single prosecution or arrest of a person shown by the computer to have obtained an illicit supply of Schedule II drugs by going "from doctor to doctor" (443a-444a).

Indeed, the Department of Health, from the outset, evidenced a monumental unconcern about the allegedly serious "doctor to doctor" problem. Although the Act was approved on June 8, 1972 and became effective on April 1, 1973, there was no memorandum which suggested that the computer might assist in solving the "doctor to doctor" problem until October 23, 1973 and even then the problem was not included in those to be answered on a "first priority basis" (93a-94a, par. 10). Similarly, when Dr. Baker testified in this case on February 11, 1974, he was not aware of any "doctor to doctor" investigations then in progress (Ex. 37,

pp. 97-8) and he had no knowledge that any such problem existed in New York State (Ex. 37, pp. 68-69).

And Assemblyman Hardt, in stating the principal purposes of the triplicate prescription provisions, did not even mention the spurious "doctor to doctor" issue (Ex. 33, p. 4):

> "At regular intervals, certain specific questions will be asked of the computer. These questions will be formulated at the highest administrative level and no question may be asked of the computer that has not been previously approved by the Department. The questions will relate to physicians who have prescribed and dispensed a greater amount of a Schedule II substance than could possibly be justified by the nature of their practice. The computer will also be asked to report on situations arising from lost or stolen prescriptions.

The questions which Assemblyman Hardt suggested be answered by computerized information (and more) can, and are, being answered without reference to the names of the patients involved. *First,* the computerization authorized by the law, even without patients' names, clearly enables the State to spot the over-prescribing physicians who concerned Assemblyman Hardt. Printouts now being produced by the system enable the Department of Health to ascertain the average amounts of each Schedule II controlled substance that is prescribed per physician (Ex. 14) and enable the State to go directly to those doctors who prescribe substantially more than the average to determine if there is a *bona fide* medical reason therefor (504a-507a).

Second, another printout shows lost or stolen prescription blanks which have been cashed (507a-508a).

Third, printouts showing two prescriptions with the same number and incorrect BNDD numbers for doctors help detect forgeries (Ex. 16; 510a-511a).

In addition, other printouts give the State valuable information as to the use of various drugs (Ex. 15; 508a-510a).

None of the above printouts contains patient names. None of the legitimate and beneficial purposes of Article 33 served by these printouts will be affected if this Court affirms the holding of the three-judge court that the portion of Article 33 requiring disclosure of patients' names violates the Due Process Clause of the Fourteenth Amendment. The State's assertion that elimination of the filing requirement "precludes any effective regulation" (Appellant's Br., p. 12) is frivolous.

3. *Similar Statutes of Other States and the Federal Government Further Demonstrate That Article 33 Was Not Narrowly Drawn to Meet Legitimate State Interests.*

The Federal government, the Commissioners on Uniform State Laws and the overwhelming majority of states which have considered triplicate prescription legislation have (unlike the State of New York) not found it necessary to intrude upon the privacy of the physician-patient relationship.

First, they did not find it "necessary" to require that the names of patients receiving Schedule II substances be filed with a centralized state agency.

Second, they did not find it "necessary" to require that the names of patients be turned over automatically but provided that such names may only be obtained based upon a showing of some relevance or necessity by the state agency.

Third, the states, federal government and Uniform Law have specific provisions to protect the physician-patient relationship.

We submit that the differences between the New York statute and the other statutes discussed below further

demonstrate that the challenged provisions of Article 33 are not justified by any "compelling state interest" and are not even reasonably related to the purposes of the Act in which they are found.

1. The Federal Drug Abuse Prevention and Control Act requires that all Schedule II drugs be dispensed pursuant to a prescription (21 U.S.C. §829(a)) and that the pharmacist retain a copy of the prescription for two years (21 U.S.C. §827(b)). Nowhere therein is the requirement (a) that the prescription be filed with the federal government or (b) that the identity of the patient using such drugs be furnished to the government. Indeed, even though there is no federal requirement of wholesale disclosure of the identities of patients, the Federal Act has two provisions specifically protecting the identities of those patients whose identities have been disclosed to the government (see 21 U.S.C. §§873(b) and 1175).

Moreover, the federal government has made clear that it can uncover abuses without the kind of invasion of patients' privacy the State is seeking to impose. The Bureau of Narcotics and Dangerous Drugs, in a January 1972 pamphlet to practitioners explaining the Controlled Substances Act of 1970 (21 U.S.C. §801, et seq.) stated (Informational Outline of the Controlled Substances Act of 1970, p. 8):

> "In order for the Bureau of Narcotics and Dangerous Drugs to curtail the diversion of controlled drugs, it is necessary for manufacturers, wholesalers, pharmacies, hospitals, and certain physicians, among others, to keep records of drugs purchased, distributed and dispensed. Having this closed system, a controlled drug can be traced from the time it was manufactured to the time it was dispensed to the ultimate user."

2. The Uniform Controlled Substances Act was adopted by the National Conference of Commissioners on Uniform

State Laws in August 1970. It contains no provision for the filing of prescriptions (or any other forms showing the identities of patients) with the State. On the contrary, the Uniform Act specifically maintains the confidentiality of the physician-patient relationship as follows (§ 504(c)):

> "A practitioner engaged in medical practice or research is not required or compelled to furnish the name or identity of a patient or research subject to the [appropriate person or agency], nor may he be compelled in any State or local, civil, criminal, administrative, legislative or other proceedings to furnish the name or identity of an individual that the practitioner is obligated to keep confidential."

Moreover, although §306 of the Uniform Act requires "practitioners" (defined in §101(t) thereof to include physicians and pharmacists) to maintain certain records, the Uniform Act very carefully provides that such records are only available pursuant to a warrant, except in limited special circumstances. Such circumstances are set forth in §502(b)(4)of the Uniform Act which reads as follows:

> "This Section does not prevent the inspection without a warrant of books and records pursuant to an administrative subpoena issued in accordance with [insert appropriate State Code section], nor does it prevent entries and administrative inspections, including seizures of property, without a warrant:
>
> (i) if the owner, operator, or agent in charge of the controlled premises consents;
>
> (ii) in situations presenting imminent danger to health or safety;
>
> (iii) in situations involving inspection of conveyances if there is reasonable cause to believe that the mobility of the conveyance makes it impracticable to obtain a warrant;

> (iv) in any other exceptional or emergency circumstances where time or opportunity to apply for a warrant is lacking; or,
>
> (v) in all other situations in which a warrant is not constitutionally required."

The Comment to the above Section states:

> "The purpose of this Section is to codify certain recent United States Supreme Court decisions, in particular *Camara* v. *Municipal Court of the City and County of San Francisco,* 387 U.S. 523 (1967), *See* v. *City of Seattle,* 387 U.S. 541 (1967), and *Colonnade Catering Corp.* v. *U. S.,* 397 U.S. 72 (1970), with regard to inspection warrants.* The Section sets out in very careful terms the procedures and restrictions for obtaining and using an administrative inspection warrant. This is of vital importance to the States since they are involved in the regulation of the legitimate drug industry and must have the ability to inspect records, books and premises if access to them is denied. By having a carefully delineated code section dealing with administrative inspection warrants, law enforcement officers will be more certain of what is needed to obtain them and the courts can apply a uniform standard. Perhaps even more important, the industry being inspected will have more certainty as to its rights and obligations in this area."
>
> "* See also: *Kramer Grocery* v. *U.S.,* 294 F.Supp. 65 (1968); and *United States* v. *Stinack* [sic] *Sales Co.,* 387 F.2d 849 (1968)."

The New York statute rides roughshod over all these considerations in requiring the automatic filing of all prescriptions for Schedule II drugs without any real possibility of judicial supervision of the process.

3. Forty states and two territories of the United States, including New York, have enacted statutes based upon the

Uniform Controlled Substances Act.* In addition to New York, only three of those states, California, Idaho and Illinois, require the filing of copies of prescriptions (which contain patients' names) with a department of the state.**

In all the remaining thirty-six states and two territories Schedule II substances may be dispensed on the written

* The remaining 39 states and two territories are as follows: Alabama (Ala. Code Tit. 22 §258(25), et seq.), Arkansas (Ark. Stats., § 82-2601, et seq.), California (Cal. Health & Safety Code, §11000, et seq.), Connecticut (Conn. Gen. Stats. Ann., §19-443, et seq.), Delaware (16 Del. Code, §4701, et seq.), Florida (Fla. Stats. Ann., §398.01, et seq.), Hawaii (Hawaii Rev. Stats., §329-1, et seq.), Idaho (Idaho Code, §37-2701, et seq.), Illinois (Ill. S.H. Ann., ch. 56½, §1100, et seq.), Indiana (Indiana Code 1971, §35-24.1-1-1, et seq.), Iowa (Ia. Code Ann., §204.101, et seq.), Kansas (Kan. Stats. Ann., §65-4101, et seq.), Kentucky (Ky. Rev. Stats., §218A.010, et seq.), Louisiana (La. Stats. Ann.—Rev. Stats., §40:961, et seq.), Maryland (Md. Code Ann., Art. 27, §276, et seq.), Massachusetts (Mass. L. Ann., ch. 94C, §1, et seq.), Michigan (Mich. Comp. L. Ann., §335.301, et seq.), Minnesota (Minn. Stats. Ann., §152.01, et seq.), Mississippi (Miss. Code Ann., 1972, §41-29-101, et seq.), Missouri (V. Ann. Mo. Stats., §195.010, et seq.), Montana (R.C.M., 1947, Ann., §54-301, et seq.), Nebraska (Neb. Rev. Stats., Supp. 1971, §28-4,115, et seq.), Nevada (Nev. Rev. Stats., §453.011, et seq.), New Jersey (N.J. Stats. Ann., §24.21-1, et seq.), New Mexico (N.M. Stats. Ann., 1953, §54-11-1, et seq.), North Carolina (N.C. Gen. Stats., §90-86, et seq.), North Dakota (N.D. Cent. Code, §19-03.1-.01, et seq.), Oklahoma (63 Okla. Stats. Ann., §2-101, et seq.), Pennsylvania (35 Penn. Stats. Ann., §780-101, et seq.), South Carolina (S.C. Code, 1962, §32-1510.21, et seq.), South Dakota (S.D. Comp. L. Ann., §39-17-44, et seq.), Tennessee (Tenn. Code Ann., §52-1408, et seq.), Texas (V. Ann. Civ. St., Art. 4476-15), Utah (Utah Code Ann., 1953, §58-37-1, et seq.), Virginia (Va. Code, 1950, §54.524.1, et seq.), Washington (Rev. Code Wash. Ann., §69.50.101, et seq.), West Virginia (W.Va. Code, §60A-1-101, et seq.), Wisconsin (Wis. Stats. Ann., §161.001, et seq.), Wyoming (Wyo. Stats. Ann., §35-347.1, et seq.); the 2 territories are: Puerto Rico (24 P.R.L. Ann., §2101, et seq.), Virgin Islands (19 V.I.C. Ann., §591, et seq.).

** Calif. Health & Safety Code §§11158, 11160, 11167; Idaho Code, §§37-2722, 37-2730, Ill. S.H. Ann., ch. 56½, §§1308, 1311, 1312(a).

prescription of the practitioner* and there is no requirement for the use of a triplicate prescription form or the disclosure of the patient's name to the State. Typically, the pharmacist is required to maintain records of prescriptions filled, in accordance with the federal law** and such additional rules as the state department may promulgate.*** Such records must be maintained for a designated period, typically two years.****

* Uniform Controlled Substances Act, §308(a); Ala. Code, Tit. 22, §258(46); Ark. Stats. §82-2616(a); Conn. Gen. Stats. Ann., §19-457; 16 Del. Code Ann., §4738; Fla. Stats. Ann., §398.07; Hawaii Rev. Stats., §329-38; Indiana Code, 1971, §35-24.1-3-8; Ia. Code Ann., §204.308; Kan. Stats. Ann., §65-4123; Ky. Rev. Stats., §218A.180; La. Stats. Ann.-Rev. Stats., §40.978; Md. Code Ann., Art. 27, §285; Mass. L. Ann., c. 94C, §17(a); Mich. Comp. L. Ann., §335.338(1); Minn. Stats. Ann., §152.11(1); Miss. Code Ann., 1972, §41-29-137(a); V.Ann. Mo. Stats., §195.060(1); R.C.M., 1947, Ann., §54-322(1); Neb. Rev. Stats. Supp. 1971, §28-4, 124(1); Nev. Rev. Stats., 453.256(1); N.J. Stats. Ann., 24:21-15 (a); N.M. Stats. Ann., 1953, §54-11-18(A); N.C. Gen. Stats., 90-106(a); N.D. Cent. Code, 19-03.1-22(1); 63 Okla. Stats. Ann., §2-309(A); 35 Penn. Stats. Ann., §780-111(a); S.C. Code 1962, §32-1510.48(a); S.D. Comp. L. Ann., §39-17-83; Tenn. Code Ann., §52-1431(a); V. Ann. Civ. St., Art. 4476-15 §3.08(a); Utah Code Ann., 1953, 58-37-6(7)(c); Va. Code 1950, §54-524.67(a); Rev. Code Wash. Ann., §69.50.308; W. Va. Code, §60A-3-308(a); Wis. Stats. Ann., §161.38(1); Wyo. Stats. Ann., §35-347.30(a); 24 P.R.L. Ann., §2308(a); 19 V.I.C. Ann., §603(a).

** The Federal statute requires that records be kept for at least two years, 21 U.S.C. §827(b)(3).

*** See e.g., Uniform Controlled Substances Act §306; Ala. Code, Tit. 22, §258(44); Ia. Code Ann., §204.306; Mich. Comp. L. Ann., §335.331(1); Miss. Code Ann., 1972, §41-29-125; Nev. Rev. Stats., §453.246; N. J. Stats. Ann., 24:21-13; N. C. Gen. Stats., §90-100; N. D. Cent. Code, §19-03.1-20; 63 Okla. Stats. Ann., §2-307; S. C. Code 1962, §32-1510.46; Tenn. Code Ann., §52-1429; Utah Code Ann., 1953, §58-37-6(1), (5); Rev. Code Wash. Ann., §69.50.306; W. Va. Code, §60A-3-306; Wyo. Stats. Ann., §35-347.23.

**** See e.g., Ia. Code Ann., §204.306 (2 years); La. Stats.-Ann. Rev. Stats. §40:976 (2 years); Md. Code Ann., Art. 27, §283 (2 years); Mass. L. Ann., ch. 94C §23(e) (2 years); Minn. Stats. Ann., §152.101(1) (2 years); V. Ann. Mo. Stats., §195.060(1) (2 years); Neb. Rev. Stats., Supp. 1971, §28-4, 122 (2 years); N. M. Stats. Ann. 1953, §54-11-16(D) (3 years); S. D. Comp. L., §39-17-82 (2 years); Va. Code, 1950, §54-524. 56(a) (2 years).

In addition, in all but thirteen of the states that do not require filing (and in both territories), the State is permitted to inspect the records of pharmacists under carefully designated conditions such as are set forth in the Uniform Act.*

Moreover, in fourteen of the non-filing states' statutes there is a provision for protection of the physician-patient relationship substantially identical to that found in the Uniform Act.**

This Court has recognized that where other states have adopted less restrictive legislation that is a factor to be considered in determining whether the challenged legislation is constitutionally justifiable (see e.g., *Doe* v. *Bolton, supra,* at 194 n.15 and accompanying text, where the Court relied on just such factors in holding unconstitutional a requirement of hospital accreditation as a pre-condition to a permissible abortion).

• • •

The State made absolutely no showing to the Court below that the massive filing of patients' names (1.5 million per

* Uniform Controlled Substances Act §502; Ark. Stats. §82-2626; Conn. Gen. Stats. Ann., §19-468; Hawaii Rev. Stats. §329-52; Indiana Code, 1971, §35-24.1-5-2; Ia. Code Ann., §204.502; La. Stats. Ann.-Rev. Stats. §40:986; Md. Code Ann., Art. 27, §294; Mass. L. Ann., ch. 94C §30; Mich. Comp. L. Ann., §335.352; Miss. Code Ann., 1972, §41-29-157; V. Ann. Mo. Stats., §195.160; Neb. Rev. Stats., Supp. 1971, §28-4, 132; Nev. Rev. Stats., §453.261; N. J. Stats. Ann., 24:21-32; N. M. Stats. Ann., 1953, §54-11-30; N. D. Cent. Code §19-03.1-33; 35 Penn. Stats. Ann., §780-124; S. C. Code 1962, §32.1510.62; Utah Code Ann., 1953, §58-37-10; Rev. Code Wash. Ann., §69.50.501-502; W. Va. Code, §60A-5-502; Wis. Stats. Ann., §161.52; Wyo. Stats. Ann., §35-347.46; 24 P.R.L. Ann., §2511; 19 V.I.C. Ann., §622.

** Uniform Controlled Substances Act §504(c); Ark. Stats. §82-2628(c); Hawaii Rev. Stats., §329-54(c); Indiana Code, 1971, §35-24.1-5-4(c); Ia. Code Ann., §204.504(3); Mass. L. Ann., ch. 94C §24(f); Mich. Comp. L. Ann., §335.354(3); Nev. Rev. Stats., §453.296; N. M. Stats. Ann., 1953, §54-11-39(D); N. D. Cent. Code, §19-03.1-35(3); 35 Penn. Stats. Ann., §780-137(c); Tenn. Code, Ann., §52-1442(c); V. Ann., Civ. St., Art. 4476-15, §5.02(c); W. Va. Code, §60A-5-504(c); cf. V. Ann. Mo. Stats., §195.260 (when not deemed privileged).

year) is warranted by some valid enforcement purpose. By June 1974, the last date for which defendant gave plaintiffs information, only two cases were thought to have been discovered of situations in which patients had gone from doctor to doctor obtaining excessive supplies of Schedule II drugs and neither of those cases resulted in detection of an actual "doctor to doctor" violation.

We submit that the Court below was plainly correct in holding that "[t]he diminution of a constitutionally guaranteed freedom is too great a price to pay for such a small governmental yield" (403 F.Supp. at 937; J.S. at 11a).

B. The State Has Failed to Take Reasonable Precautions to Maintain Security of the Computerized Information.

In its opinion herein, the Court of Appeals held that even if there were some need for the challenged provisions, the State could be required to take reasonable precautions to limit the risk to privacy, stating (480 F.2d at 108-9; 53a):

> "Without questioning the seriousness of the problem [of drug abuse], plaintiffs respond that these abuses could be adequately controlled without central filing, or by central filing without patient's names, and that the added efficiency is not worth the price in terms of risk of disclosure.
>
> On this last point something turns on how great the risk is. While the Constitution does not condemn a state to using ineffective means in dealing with a problem as serious as the use of the opiates and stimulants listed in Schedule II, it may well condition use of a more effective means which involves a danger to constitutionally-protected privacy on the taking of all reasonable precautions to limit the risk."

Accordingly, the Court remanded for "further exploration of the degree of need for central filing including the patients' names on the one hand, and the adequacy of the provisions

to protect against careless or malicious disclosure on the other" (480 F.2d at 109; 54a).

The three-judge court, finding no need for the challenged provisions, concluded that "[t]he bases for our decision make unnecessary an evaluation of the operative state measures to insure confidentiality" (403 F.Supp. at 938; J.S. 13a).

For the same reason—the lack of any need for the challenged provisions—we respectfully submit that this Court, too, need not consider the reasonableness of the State's precautions to limit the risk of disclosure of confidential information. Nevertheless (and without conceding the existence of any need) so that this Court will have all salient facts before it we turn to a consideration of the question of security.

1. *The Executive Branches of Federal and State Governments Have Not Been Able to Maintain Security of Confidential Information.*

Preliminarily we note that, for whatever reason, recent times have provided an unprecedented plethora of examples of governmental abuses threatening the individual's right of privacy, Senate Report No. 93-1183, *supra*, at 65. These include the attempt to steal the records of Dr. Ellsberg's psychiatrist (see e.g., N. Y. Times, April 28, 1973, at p. 1, col. 4), the revelation of a government-compiled "enemies list" of individuals selected for harassment or disfavor (see e.g., N. Y. Times, June 27, 1973, at p. 49, cols. 1-2; N. Y. Times, June 28, 1973, at p. 1, col. 5) and repeated allegations that military and law enforcement agencies have collected massive dossiers of persons engaged in political activity (see e.g., The Washington Post, January 19, 1975, at p. A-1, col. 7 [FBI dossiers on members of Congress] and The Washington Post, December 24, 1974, at p. A-1, col. 7 [allegations of CIA surveillance of domestic political activity]).

The unauthorized release of confidential information has also been common (see generally, Hearings on H.R. 9527 and Related Bills Before a Subcomm. of the House Comm. on Government Operations, 92nd Cong. 2d Sess. (1972) at pp. 92-3, 216 relating to such release of confidential information by governmental employees, and by the FBI).

There have been similar reports relating to New York State Government and the New York Department of Health. In March 1973, New York State Senator Joseph R. Pisani, Republican of Westchester, was quoted as stating, with regard to the illusory nature of security of the information required to be filed under the new triplicate prescription drug law which was about to go into effect at that time: "Why, I've obtained information that the State lists as confidential" (New York Times, March 18, 1973, p. 64, col. 1).

On January 1, 1975, the New York Times published excerpts from a memorandum from Dr. Andrew C. Fleck, Jr., First Deputy Commissioner in charge of medical-care services, concerning the Park Crescent Nursing Home (New York Times, p. 1, col. 8 and p. 15, cols. 1-4). The Times reported that "Dr. Fleck denounced the leak."*

It is well recognized that, notwithstanding the prohibition on inspection of family court files and New York City regulations on confidentiality, highly sensitive arrest and police records have routinely been made available to outsiders. See generally *In the Matter of Earl Smith and Ricardo Vasquez,* 310 N.Y.S.2d 617, 620 (Fam.Ct., N.Y.Co.

* Similarly, on September 17, 1973, under the headline "Hogan: Stroke and Lung Cancer", the New York Post published a photocopy of the supposedly confidential medical record maintained by St. Luke's Hospital with respect to Frank Hogan, then District Attorney of New York County. On the following day, the New York Times reported that the Executive Vice-President of St. Luke's Hospital said he was "incensed"; that the hospital was conducting an investigation into "leaks of medical records"; and that "files covering a three week period had somehow been uncovered or copied." (New York Times, September 18, 1973, p. 1, col. 5-6.)

1970); see also *Menard* v. *Mitchell,* 328 F. Supp. 718, 721-2 (D.D.C. 1971).

Another telling illustration of the lack of security of information gathered and "protected" by the State is the damning "Audit Report on Financial and Operating Practices of the New York State Identification and Intelligence System" prepared by the Office of the Comptroller of the State of New York (Ex. 29). Although a different system than the one here at issue, it too is maintained by the State of New York and the need for absolute security in the maintenance of the information it contains, fingerprint and criminal identification files, is also obvious. Yet the Office of the Comptroller found that the State knowingly permitted representatives of the United States Army and Navy to roam at will through the fingerprint files of the New York State Intelligence and Identification System even though they were not authorized to do so under the law (Ex. 29, pp. 6, 24-5). The report stated (Ex. 29, p. 6):

> "Personnel from the United States Army and Navy are permitted to search the files although these agencies are not specified in Article 21 of the Executive Law as authorized agencies."

In addition, the Comptroller's Office found serious security problems ranging from the location of the facility in a private office building to the lack of a formal training program and security clearance program for personnel with access to the confidential information (Ex. 29, pp. 2, 26-33).

2. *The Evidence Demonstrates That the System to Safeguard the Confidential Information Collected under Article 33 Is Entirely Inadequate.*

The evidence in this case confirms the illusory nature of the "security" of the computerized information held by the Department of Health. The only evaluation of the

State's system came from Mr. Joseph J. Wasserman, an acknowledged expert in the area of security of computerized data (297a-300a; Ex. 41). Mr. Wasserman, who examined the State's computer facility in Albany, concluded that security there was entirely inadequate and that there was a substantial risk of unauthorized disclosure of the triplicate prescription information maintained there (321a).

For example in addition to inadequate physical protection against unauthorized access, Mr. Wasserman observed the most obvious defects in the systems and procedures as to the manner in which access to the data center was to be protected. There were no background, drug or credit checks made of personnel handling the information, no periodic re-checks of employees, and no checks of personnel not employed by the Department of Health (e.g., personnel charged with maintenance of computers) (308a, 304a, 333a-334a). Temporary employees were employed in sensitive areas. Such failures contravene the most elementary business security proecedures (308a-309a).

Other such failures in the system included the absence of any on-going program for computer security to insure that the employees will not forget that they are working with confidential data (342a-343a); the failure to provide any security manual (309a, 312a, 334a-335a); and the failure to encrypt or encode sensitive items of information so that they cannot simply be printed out by anyone who gains access to the computer (313a, 335a-336a).

Additional failings noted by Mr. Wasserman included inadequate storage facilities (313a-314a, 340a, 357a-358a); lack of procedures for shredding printouts (315a, 340a-341a); failure to require presence of a representative of management when computer operations with respect to triplicate prescription operations were run (341a, 316a) to be sure that the tape was not being duplicated (316a);

failure to erase memory of the computer after processing of the prescription information (341a, 314a-315a); leaving data in disc form in the machine overnight (314a); and absence of controls for printed reports delivered from one area to another (315a-316a).

No witness proffered by the State was (or purported to be) an expert in assuring the security of computerized information. No witness had the temerity to assert that the State's security system was adequate. The State has carefully avoided any discusion of the efficiency of its security system in its brief to this Court and the best it could claim to the Court below was that "Mr. Wasserman's thoughts are of value, and indeed many have been implemented" (Defendant's Post-Trial Br., p. 28). But Mr. Wasserman, who heard all the testimony of Messrs. Bonacci and Cannizzaro as to such "implementation", testified that such testimony did not change his conclusion that the State's security system was wholly inadequate (329a), and that the vast majority of his suggestions were not implemented (329a-346a).*

The spurious nature of the State's "security system" was further confirmed by the fact that many of the very same criticisms made by Mr. Wasserman had been in the Comptroller's Report as to the security of the New York State Intelligence and Identification System (Ex. 29, pp. 27-31; 317a-319a). Nevertheless, no steps had been taken by the Department of Health to implement suggestions contained

* The State cites the provisions of § 3370 requiring destruction of records within five years (Appellant's Br., pp. 32, 33, 34, 37, 39, 46, 47). The cited section (enacted in response to this action), however, merely requires destruction of "any record received by [the Department of Health] pursuant to the filing requirements of" §§3331(6), 3333(4) and 3334(4). The records referred to are the official New York State prescription forms, *not* the tapes or any other records made therefrom. Moreover, a further provision of §3370 authorizes the copying of such records by other state licensing and regulatory officials and there is no provision for destruction of those copies (see §3370(2)).

therein such as guards, a formal training program, a badge identification system and numerous other suggestions made in 1971 (318a-319a).

Moreover, neither Mr. Cannizzaro nor Mr. Bonacci had any understanding as to why the Schedule II information should be kept confidential, apart from the requirements of the Act (478a-479a; Bonacci Tr. Dep. 73-75). Both testified in their view the computerized centralization of data did not increase the risk of unauthorized disclosure (479a; Bonacci Tr. Dep. 73-75). As Mr. Wasserman remarked, when security programs are left under the supervision of individuals who do not understand the increased threat to privacy resulting from the fact that large quantities of information can be stored on a few reels of tape, that attitude in itself must considerably lessen the effectiveness of security procedures (344a-345a).

The State's indifference to security problems (except as a temporary tactical expedient in connection with this action*) was further demonstrated by the fact that Mr. Cannizzaro, who is charged with the responsibility of deciding when to turn over information to Mr. Bellizzi, head of the Bureau of Narcotic Control, did not even know the manner in which the Bureau of Narcotic Control utilized the information which he provided (428a-429a). Under these circumstances, it is difficult to comprehend how Mr. Cannizzaro could make a rational determination as to whether to turn information over to Mr. Bellizzi.

Finally, Mr. Wasserman has testified that *no* computer system is absolutely safe (323a). Many factors within the system may change in ways which create serious dangers of disclosure. The present computerized system, the security regulations, the administrative structure, the computer

* Mr. Bellizzi frankly admitted that in the absence of this action he would have always had free access to all the computerized data, without having to go through Mr. Cannizzaro (Ex. 39, at p. 71).

program and so forth are not mandated by the Act. The number of employees may change. Investigative techniques may be used by the State in ways which give many persons access to the information. The present list of printouts may be increased so that all patients' names are printed out for investigative purposes. The system could be tied into the federal computerized system by force of federal law.* Many of these changes are beyond the continuing scrutiny of the courts or of any person outside the State government.

3. *Article 33 Does Not on Its Face Insure Confidentiality.*

The State, relying principally on §3371, argues that the Act on its face insures the confidentiality of the triplicate prescription data (Appellant's Br., pp. 32-35). Yet, as was made clear by Judge Friendly in his opinion in this case, the mere enactment of a section purporting to prevent disclosure cannot immunize the statute from constitutional attack. Rather, the State must demonstrate that it has taken "all reasonable precautions" to insure confidentiality by statute, regulation or otherwise (53a; 480 F.2d at 109). The Act as drafted and amended cannot insure the required degree of confidentiality.**

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* Both Mr. Bonacci, present head of OEDP for the Department of Health, and his predecessor Mr. Gottheim, have testified that, although the triplicate prescription data is not presently connected to terminals outside the office building in Albany where the computer tapes are kept, several other types of information maintained by the State are connected to approximately 22 different terminals (Bonacci Tr. Dep. 77; Gottheim in Ex. 40, p. 22) and it would be a simple matter to make the mechanical adjustments necessary to provide terminal access to computerized triplicate prescription information (Bonacci Tr. Dep. 39-40; Gottheim in Ex. 40, p. 85).

** While amendment of the statute has cured the ambiguity criticized by Judge Friendly (Appellant's Br., pp. 32-35), we show herein that this is only one example of the generally "open-ended" (53a; 480 F.2d at 109) nature of the statute that in Judge Friendly's view rendered it ineffective as a means of insuring confidentiality.

First, regardless of the Act, as shown above there is no need for this collection of vast volumes of personal data (*supra,* pp. 37-53) and the uncontradicted evidence at trial was that under the State's existing security arrangements the danger of unauthorized access is substantial (*supra,* pp. 56-60).

Second, the Act's limits on both disclosure within the Department and inter-agency transfer of the triplicate prescription data are open-ended. Transfer within the Department is required only to be "for purposes of executing provisions of this article" and inter-agency transfer is virtually unlimited provided the agency is one "authorized to regulate, license or otherwise supervise a person who is authorized by this article to deal in controlled substances or in the course of any investigation or proceeding by or before such agency, department or board." As to the dangers of inter-agency data transfer, see S. Rep. No. 93-1183, *supra,* p. 24.

Third, a revealing contrast is provided by the Federal Privacy Act (5 U.S.C. §552a) which applies to all individual records maintained by the federal government (§552a(a)(4)) and thus extends to records much less sensitive than individual medical records.

The Privacy Act (1) requires federal agencies to maintain an accurate accounting of disclosures of individual records (described in S. Rep. No. 93-1183, *supra,* at p. 53 as "an essential element of the Code of Fair Information Practice") (5 U.S.C. § 552a(c)); (2) requires individual access to records (§ 552a(d)); (3) requires agencies to establish rules of conduct for persons involved with individuals' records, to instruct such individuals in the requirements, and "to establsh appropriate administrative, technical, and physical safeguards to insure the security and confi-

dentiality of records" (§§ 552a(e)(9)(10)); and (4) provides individuals with a civil remedy when an agency fails to comply with privacy provisions (§ 552(g)(1)).

Similarly, the federal "Professional Standards Review" law (47 U.S.C. § 1320c), at issue in a case relied upon by the State (Appellant's Br., pp. 19-20, 33-35), *Association of American Physicians & Surgeons* v. *Weinberger,* 395 F. Supp. 125 (N.D. Ill. 1975), *aff'd sub nom., Association of American Physicians & Surgeons* v. *Mathews,* —— U.S. ——, 96 S. Ct. 388 (1975) requires, as the court therein noted, utilization of "methods of coding which will provide maximum confidentiality as to patient identity." (395 F. Supp. at 130, 135). In the instant case, Article 33 does not require coding, and the State does not carry out such coding in practice (313a, 335a, 407a-408a).

In the case of records relating to drug abuse prevention, federal law (21 U.S.C. §1175) also provides a much greater degree of confidentiality than does §3371. Thus, without a patient's permission, such records may be disclosed only in *bona fide* medical emergencies, for the purpose of research and audits providing patient indentities are not disclosed directly or indirectly, and upon court order (21 U.S.C. §1175(b)(2)). Use of such records in criminal investigations of patients is specifically prohibited (21 U.S.C. §1175(c)). In addition a comprehensive set of regulations (42 C.F.R. §§2.1-2.67-1) has been promulgated to implement 21 U.S.C. §1175. See also 21 U.S.C. §873(b). By contrast, Article 33 specifically permits access in criminal investigations (§3371(b)).

In short, none of the elemental safeguards of the federal statutes are present to protect confidentiality of records collected under Article 33, the statute itself allows open-ended inter-agency transfer, and no viable security has been provided for the records.

POINT IV

Plaintiffs herein Clearly Have Standing to Sue.

To a large extent, the State's arguments regarding plaintiffs' standing to sue merely repeat its arguments on the merits.* To the extent that appellant does challenge plaintiffs' standing to bring the instant action, the State's arguments were properly rejected by both the Court of Appeals when it directed that a three-judge court be convened and the three-judge court when it denied appellees' motion for a preliminary injunction. Thus, the three-judge court stated (364 F. Supp. at 540, n. 6):

> "6. The physicians are not here merely asserting the rights of their patients but claim independent violations of protected constitutional rights. *Their standing to sue is established by Doe* v. *Bolton,* 410 U.S. 179, 93 S.Ct. 739, 35 L.Ed.2d 201 (1973). *See also, Roe* v. *Ingraham,* 480 F.2d 102 (2d Cir. 1973), at n. 5. Although it is unclear from the complaint, the Physicians Guild is apparently suing on behalf of its doctor members. Inasmuch as its claims are only repetitive, we may assume proper standing exists. Griswold v. Connecticut, 381 U.S. 479, 85 S.Ct. 1678, 14 L.Ed.2d 510 (1965), NAACP v. Alabama, 357 U.S. 449, 78 S.Ct. 1163, 2 L.Ed.2d 1488 (1958); Pierce v. Society of Sisters, 268 U.S. 510, 45 S.Ct. 571, 69 L.Ed. 1070 (1925)" (emphasis added).

And Justice Marshall stated in denying the State's application for a stay: "Likewise, the court's conclusion that respondents had standing seems in accord with the liberal standing decisions of this Court" (J.S. 43a).

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* For example, "[C]entralized collection, as a means of furthering a legitimate state objective, is not an invasion of privacy, and thus any challenge to same does not present a real case." (Appellant's Br., p. 42).

Nor can it seriously be disputed that the physicians and the patients who are plaintiffs herein have the required "personal stake in the outcome of the controversy", *Baker* v. *Carr,* 369 U.S. 186, 204 (1962), and that there is a "logical nexus between the status asserted and the claim sought to be adjudicated," *Flast* v. *Cohen,* 392 U.S. 83, 95 (1968). See also *Buckley* v. *Valeo,* ——U.S.——, 96 S.Ct. 612, 631 (1976).

The present statute interferes with the freedom of the physician plaintiffs to practice medicine according to the highest medical standard, *Doe* v. *Bolton,* 410 U.S. 179, 199 (1973); *Nyberg* v. *City of Virginia,* 361 F.Supp. 932, 936 (D.Minn. 1973), *aff'd* 495 F.2d 1342 (8th Cir. 1974). Thus, the *Roe* complaint alleges that the statute "infringes on the doctor's right to prescribe treatment for his patients solely on the basis of medical considerations" (11a at par. 11). And the uncontradicted record proof in this case is that a plaintiff psychiatrist terminated the use of Schedule II drugs which he deemed helpful to patients suffering from certain psychiatric disorders because the fears created by the filing requirement would undermine the patient's trust and confidence in the psychiatrist (154a-155a, 168a-169a), and that it became impossible for several physician plaintiffs to use Schedule II drugs in treating patients who needed such drugs after patients learned of the filing requirements (177a-181a, 186a-187a, 213a-214a).

A further basis for the standing of the physician plaintiffs is that the physician is the one against whom the license revocation sanctions of Article 33 operate if he prescribes or dispenses Schedule II drugs without causing a prescription form containing the patient's name to be filed in Albany (§3390(2)). See *Doe* v. *Bolton,* 410 U.S. 179, 188-9 (1973); *Abele* v. *Markle,* 452 F.2d 1121 (2d Cir. 1971); *Nyberg* v. *City of Virginia,* 361 F.Supp. 932, 936 (D.Minn.

1973), *aff'd* 495 F.2d 1342 (8th Cir. 1974). Here, as in *Doe* v. *Bolton, supra,* there is, thus, a "sufficiently direct threat of personal detriment" (410 U.S. at 188).

The facts that the patient plaintiffs have not suffered economic injury and that many other persons are also injured do not deprive plaintiffs of standing. *United States* v. *SCRAP,* 412 U.S. 669, 686 (1973). In the *SCRAP* case, the injury alleged was that the failure of the Interstate Commerce Commission to suspend a 2.5% rate increase might adversely affect plaintiffs' "use and enjoyment of the natural resources of the Washington area" (p. 687). This Court summarized the "attenuated line of causation to the eventual injury" alleged by plaintiffs as follows (p. 688):

> "Here the Court was asked to follow a far more attenuated line of causation to the eventual injury of which the appellees complained—a general rate increase would allegedly cause increased use of nonrecyclable commodities as compared to recyclable goods, thus resulting in the need to use more natural resources to produce such goods, some of which resources might be taken from the Washington area, and resulting in more refuse that might be discarded in national parks in the Washington area."

Nevertheless, this Court held that plaintiffs had standing and explained its earlier holding in *Sierra Club* v. *Morton,* 405 U.S. 727 (1972) as follows (at pp. 686-7):

> "Nor, we said, could the fact that many persons shared the same injury be sufficient reason to disqualify from seeking review of an agency's action any person who had in fact suffered injury. Rather, we explained: 'Aesthetic and environmental well-being, like economic well-being, are important ingredients of the quality of life in our society, and the fact that particular environmental interests are shared by the many rather than the few does not make them less

deserving of legal protection through the judicial process.' Id., at 734."

And further (p. 689, fn. 14):

"The Government urges us to limit standing to those who have been 'significantly' affected by agency action. But, even if we could begin to define what such a test would mean, we think it fundamentally misconceived. 'Injury in fact' reflects the statutory requirement that a person be 'adversely affected' or 'aggrieved,' and it serves to distinguish a person with a direct stake in the outcome of a litigation—even though small—from a person with a mere interest in the problem. We have allowed important interests to be vindicated by plaintiffs with no more at stake in the outcome of an action than a fraction of a vote, see Baker v. Carr, 369 U.S. 186; a five-dollar fine and costs, see McGowan v. Maryland, 366 U.S. 420; and a $1.50 poll tax, Harper v. Virginia Bd. of Elections, 383 U.S. 663. While these cases were not dealing specifically with §702 of the APA, we see no reason to adopt a more restrictive interpretation of 'adversely affected' or 'aggrieved.' As Professor Davis has put it: 'The basic idea that comes out in numerous cases is that an identifiable trifle is enough for standing to fight out a question of principle; the trifle is the basis for standing and the principle supplies the motivation.' Davis, Standing: Taxpayers and Others, 35 U. Chi. L. Rev. 601, 613. See also K. Davis, Administrative Law Treatise §§22.09-5, 22.09-6 (Supp. 1970)."

Here, the patient plaintiffs are aggrieved in a direct, substantial and specific manner. Their right to private medical advice is not infringed by any "attenuated line of causation" such as the Court referred to in the *SCRAP* case. The challenged provisions of the Act, by requiring that a prescription form be filed with the State which contains, *inter alia*, the patient's name, address, age, medication and physician, clearly and directly invade the patient's privacy by requiring disclosure of intimate information to the State (see pp. 20-25 *supra*).

In *California Bankers Assn.* v. *Shultz*, cited by appellant (Appellant's Br., pp. 46-47), the Court held that the depositor plaintiffs lacked standing to challenge the domestic reporting provisions of the Bank Secrecy Act, as effectuated by regulations which required banks to report currency transactions in excess of $10,000 "because there was no allegation by any individual depositor that they were engaged" (416 U.S. at 68) in such a transaction. The Court stated (416 U.S. at 67-8):

"In addition to the Fourth Amendment challenge to the domestic reporting requirements made by the bank plaintiffs, we are faced with a similar challenge by the depositor plaintiffs, who contend that since the reports of domestic transactions which the bank is required to make will include transactions to which the depositors were parties, the requirement that the bank make a report of the transaction violates the Fourth Amendment rights of the depositor. The complaint filed in the District Court by the ACLU and the depositors contains no allegation by any of the individual depositors that they were engaged in the type of $10,000 domestic currency transaction which would necessitate that their bank report it to the Government. * * * [W]e simply cannot assume that the mere fact that one is a depositor in a bank means that he has engaged or will engage in a transaction involving more than $10,000 in currency, which is the only type of domestic transaction which the Secretary's regulations require that the banks report. That being so, the depositor plaintiffs lack standing to challenge the domestic reporting regulations, since they do not show that their transactions are required to be reported."

In the present case, every one of the patient plaintiffs testified that he, or the child for whom he brought this

action, had been prescribed Schedule II drugs and thus were engaged in the type of event that would result in their physician or pharmacist reporting it to the State government (117a-118a, 137a-138a, 140a-141a, 196a, 211a-212a).

Moreover, the injury to plaintiffs herein is far more serious than that alluded to by the two concurring and three dissenting justices in *Shultz* and the majority in *SCRAP*. As shown at length above (pp. 20-25), the reporting requirements of the Act clearly "touch upon intimate areas of an individual's personal affairs" (Powell, J. concurring in 416 U.S. at 78). The Court of Appeals herein has already taken judicial notice of the fact that an individual's prescriptions often reveal the nature of his ailment (see 480 F.2d at 108, n.7). As a result of the challenged statute, such information about thousands of individuals is transmitted to the State without the necessity of a warrant or any opportunity for a patient to prevent its transmittal. As Justice Powell said "the potential for abuse is particularly acute where . . ., the legislative scheme permits access to this information without invocation of the judicial process" (416 U.S. at 79).

With regard to the plaintiff physician's organizations, we submit that their standing to assert claims on behalf of their members to practice medicine according to the highest medical standards is analagous to that of an organization to "assert, on behalf of its members, a right personal to them to be protected from compelled disclosure of their affiliation . . ." *NAACP* v. *Alabama,* 357 U.S. 449, 459 (1958) quoted in *Buckley* v. *Valeo, supra,* at 96 S. Ct. 631 n. 10.

Appellant relies on this Court's decision in *Laird* v. *Tatum,* 408 U.S. 1 (1971) in arguing that the instant plaintiffs lack standing. However, in that case the Court described the challenged action as "the threat . . . that *in some future civil disorder* of some kind, the Army is going

to come in with its list of troublemakers . . . and go rounding up people and putting them in military prisons somewhere" (emphasis in original) (408 U.S. at 9 n. 5). The Court in summarizing past standing decisions stated (408 U.S. at 11):

> "[I]n each of these cases, the challenged exercise of governmental power was regulatory, proscriptive, or compulsory in nature, and the complainant was either presently or prospectively subject to the regulations, proscriptions, or compulsions that he was challenging."

In the instant case, plaintiffs' challenge is directed at the present compulsory collection of data for prescriptions of Schedule II drugs for the plaintiff patients prescribed by the plaintiff doctors. See *Lamont* v. *Postmaster General,* 381 U.S. 301 (1965) discussed in *Laird* v. *Tatum, supra,* at 12.

Appellant also relies on *Schlesinger* v. *Reservists Comm. to Stop the War,* 418 U.S. 208 (1974). In that case, this Court reaffirmed its prior decisions regarding plaintiffs who urged only their status as citizens and taxpayers in challenging federal statutes on constitutional grounds. In the present case, plaintiffs do not rely on such status but rather on their status as doctors and patients directly affected by the triplicate prescription program.

Under these circumstances, we submit the Court below was clearly correct in holding that plaintiffs herein had standing to sue.

Conclusion

The State has failed to demonstrate any need ("compelling" or otherwise) which justifies its system of continued monitoring of persons who take Schedule II drugs under the supervision of licensed physicians, for no reason other than to relieve pain and mitigate the effects of serious disease. On the contrary, the uncontradicted record proof in this case shows that the centralized collection of patients' names is not necessary or even appropriate to detect over-prescribing physicians, over-dispensing pharmacists or individuals who forge or steal prescription blanks. And as to individuals who supposedly go from "doctor to doctor" to obtain excessive amounts of Schedule II drugs (which persons, the State continues to assert, its system will aid in detecting), the record proof is also uncontradicted that such cases have been utterly insignificant historically (4 cases in the 7 years prior to trial) and have continued to be *de minimis* since institution of the present system (2 case reports referred for investigation).

We submit that Article 33's filing provisions violate the reasonable expectations of thousands of citizens that they may keep to themselves the nature of their treatment and illnesses and may maintain the confidentiality of communications with their physicians. There is and can be no reasonable basis for suspecting the overwhelming majority of persons utilizing Schedule II drugs or for prying into their personal affairs. The suggestion that the State has a security system which will preserve the confidentiality of such information is belied by the evidence in this case as well as by the innumerable examples of leaks of supposedly confidential information at all levels of our government.

We urge that the State's system is a totally unjustified intrusion into what Justice Brandeis described in his dissent in *Olmstead* v. *United States*, 277 U.S. 438, 478 (1928),

as "the right to be let alone—the most comprehensive of rights and the right most valued by civilized men."

For the reasons set forth above and based upon the evidence adduced at trial, appellees submit that this Court should affirm the final order and judgment of the Court below permanently enjoining enforcement of, and declaring unconstitutional, those provisions of Article 33 of the New York Public Health Law which require physicians to record the identity of their patients on copies of prescription forms filed with the State.

Respectfully submitted,

Dated: New York, New York
July 16, 1976

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* The able assistance of Marilyn Marlek of the Georgetown University Law Center is acknowledged.

ADDENDUM

PRE-TRIAL ORDER NO. 2 ON CONSENT

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

RICHARD ROE, an infant, by ROBERT ROE, his parent, et al.,
Plaintiffs,

and

GEORGE PATIENT, et al.,
Intervenors,

against

HOLLIS S. INGRAHAM, as Commissioner of Health of the State of New York,
Defendant.

On November 19, 1974, the attorneys for the parties to this action appeared before the Court at a pre-trial conference pursuant to Rule 16 of the Federal Rules of Civil Procedure and, as a result thereof, the following action has been taken:

1. The testimony of plaintiffs' expert witnesses and defendant's witnesses will be submitted to the Court in deposition form, which depositions will be held at the offices of Shea Gould Climenko & Kramer at the following times, unless the parties agree otherwise:

Dr. Jerry M. Rosenberg	—December 4, 1974, commencing at 9:30 A.M.
Joseph Wasserman	—December 4, 1974, commencing at 2:00 P.M.
Joseph L. Cannizzaro	—December 5, 1974, commencing at 9:30 A.M.
Joseph Bonacci	—December 5, 1974, commencing at 2:00 P.M.
Joseph Wasserman (rebuttal)	—December 6, 1974, commencing at 9:30 A.M.

Pre-Trial Order No. 2 on Consent

2. Post-Trial Proposed Findings of Fact and Conclusions of Law and briefs of all parties will be submitted no later than four weeks after the parties' attorneys have received copies of the trial transcript and of the transcripts of the above depositions. Within two weeks after all such papers have been submitted, all parties shall submit post-trial reply briefs, if any.

3. The Pre-Trial Order on Consent made herein on November 18, 1974 remains in full force and effect, except as modified hereinabove.

/s/ Robert L. Carter
U.S.D.J

Dated: New York, New York
November 21, 1974

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Supreme Court, U. S.
FILED
JUL 16 1976
MICHAEL RODAK, JR., CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1975

No. 75-839

ROBERT P. WHALEN, as Commissioner of Health of the State of New York,

Appellant,

—against—

RICHARD ROE, an Infant, by ROBERT ROE, his Parent; JOHN DOE, an Infant, by MARY DOE, his Parent; JAMES MOE, an Infant, by MICHAEL MOE, his Parent; JANE POE, MATTHEW T. BRODY, ISRAEL L. SCHMIERER and EMPIRE STATE PHYSICIANS GUILD, INC.,

Appellees,

—and—

GEORGE PATIENT, MARTHA PATIENT, GERALD L. LUSTIG and THE AMERICAN FEDERATION OF PHYSICIANS AND DENTISTS,

Intervenor-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

APPELLEES' BRIEF

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In the

SUPREME COURT OF THE UNITED STATES

October Term, 1975

No. 75-839

ROBERT P. WHALEN, as Commissioner of the State of New York,

Appellant,

- against -

RICHARD ROE, et al.,

Appellees,

- and -

GEORGE PATIENT, et al.,

Intervenor-Appellees.

On Appeal from the United States
District Court for the
Southern District of New York

APPELLEES' BRIEF

This brief is submitted on behalf of appellees George Patient, Martha Patient, Dr. Gerald Lustig and the American Federation of Physicians and Dentists, plaintiffs in the case of Whalen v. Patient consolidated with Whalen v. Roe below.

This is an action brought by a number of doctors and patients challenging the requirement of a state statute that the names of all patients receiving duly prescribed medically indicated ("Schedule II") drugs be reported to and centrally filed with the state. The Commissioner of the Department of Health appeals from a judgment of a three-judge District Court which limited one provision of a comprehensive state statute (New York Public Health Law §3300 et seq.) which regulated drug manufacture, distribution, research, dispensing and record-keeping. The District Court, reviewing the asserted need for the central reporting of all patient names, invalidated the requirement that the name appear on that copy of the prescription which was transmitted to the Department of Health in Albany. The District Court did not invalidate any part of the entire balance of the statute which remains intact.

QUESTION PRESENTED

Where the trial court in reviewing a state statute requiring the central filing and computerization of the names of all patients receiving duly prescribed medically indicated drugs found after hearing extensive evidence that:

a) the centralized filing of names discouraged patients from using medically indicated drugs and the patients had suffered real harm including diminished effectiveness of treatment or increased pain; and

b) the state was able to monitor drug use and achieve the purposes contemplated by the statute without collecting the name of every patient,

did the trial court err in narrowing the state's system by invalidating the provision that patient names be included on the centrally filed form?

STATEMENT OF CASE

1. Procedural History.

The Commissioner of Health of the State of New York appeals from a unanimous judgment of a three-judge federal District Court dated August 13, 1975, which declared unconstitutional and enjoined those provisions of the New York State Public Health Law (§§3331(b), 3332(2)(a) and 3333(4)) which required that the name and other identifying information of every patient prescribed Schedule II drugs (§3306) be filed centrally with the state. The Court's decision was reached only after the most extended consideration and review by that Court, the original District Court and the Second Circuit Court of Appeals.

This case began when two separate complaints were filed in March and April 1973. Plaintiffs in the initial action are four patients - three children, and an adult receiving duly prescribed Schedule II medication - as well as two doctors who prescribed these drugs. The second action was brought by two patients - a post-operative cancer patient and a person suffering from migraine headaches, both of whom received Schedule II medication - the doctor of one of these patients and a federation of physicians and dentists. After these two actions were consolidated, the State Department of Health moved to dismiss for want of a substantial federal question. In April 1973, after argument, the District Court, Judge Robert Carter, granted the state's motion. (357 F. Supp. 1217 (1973)).

In his opinion Judge Carter, the judge who also wrote the decision appealed from here, reviewed the legislative scheme and held -- without benefit of the extensive record later produced at trial -- that there was no substantial federal question in that the program was apparently designed to help effectuate the asserted state purpose and that the invasion of the doctor-patient relationship appeared minor.

On appeal the Second Circuit reversed, finding in a unanimous opinion by Judge Friendly that a substantial constitutional question had been raised by the complaint. It remanded the case for consideration by a three-judge Court. (480 F.2d 102 (1973)). However, the Second Circuit placed a heavy burden of proof on the plaintiffs. Recognizing that "New York has

advanced powerful arguments in support of the central filing of prescriptions," (52a) the Court remanded for a review of the question of the need for central filing including patients' names.

Thereafter, a three-judge Court was convened. In August 1973 the plaintiffs moved for a preliminary injunction and the defendants cross-moved to dismiss. Both motions were denied. In ruling on plaintiffs' motion, the three-judge Court had only the allegations made in the complaints and the initial affidavits. In its denial of plaintiffs' motion, the Court again stressed the requirement that plaintiffs prove that their rights to privacy had in fact been affected and that their consequent injuries were not justified by the state interest. (364 F. Supp. 536 (1573)).

The case was tried before this same three-judge District Court in December 1974. At trial the Court received in evidence plaintiffs' testimony, a lengthy stipulation of facts, depositions and exhibits. Based on the extensive record before it, the three-judge Court ruled unanimously in August 1975 that the reporting of names was an unconstitutional interference with the plaintiffs' right of privacy. (Jurisdictional Statement 13a (JS)) The Court enjoined such filing. The Court also ordered the expungement of past patient name records but stayed that portion of the order pending appeal.

Justice Marshall, on the state's motion to stay the judgment of the District Court pending appeal, refused after oral

argument to vacate the lower court injunction. He continued the stay of expungement.

2. Findings of Fact.

The three-judge Court's findings of facts were:

A. The Existence of a Massive Computerized System

The statute requires physicians prescribing Schedule II drugs to do so on triplicate forms, one of which is sent to the State Bureau of Controlled Substances Licensing (State Bureau). Included on the form are the name and address of the patient, the Drug Enforcement Administration (DEA) number of the prescribing physician, the date on which the prescription was issued, the name and the amount of the drug prescribed, the maximum daily dosage, the National Drug Code number, and numbers identifying the dispensing pharmacy. The State Bureau receives 100,000 such prescriptions per month (J.S. 4a), and with the help of nine clerks and 20 odd other personnel processes these prescriptions onto computer tapes. In the 20 months prior to the entry of judgment the state had received 2,000,000 prescriptions.

B. Clear Harm to Patients

Schedule II substances include a variety of drugs, all of which are recognized as having legitimate medical uses. These drugs are used to alleviate chronic pain associated with pre-operative and post-operative cancer conditions and with migraine

conditions as well as to treat such diseases as schizophrenic disorders, epilepsy, narcolepsy and childhood hyperkinesis. (Dr. Brody, 148a-153a). The Court found that as a result of the system patients had substantially changed their medical treatment. Several patients testified to their deep concern about stigmatization of their children who as a result of taking ritalin, a Schedule II drug used to treat hyperkenesis, would have a record of drug use kept by the state. (J.S. 6a) Several, such as Mary Doe, a plaintiff, felt compelled to remove their children from treatment.* Another plaintiff stopped taking medication and was

* She testified:

A. "I took him off the drug, even though the doctor advised me not to.

Q. What was the immediate effect on your son's conduct after you took him off the drug?

A. Well, he has no -- he had no control over himself. He did very poorly in school. He was left back. He lost a full year in school because of his inability to have a long term period of concentration in the classroom. He was disruptive. He was completely changed.

Q. Have you ever permitted him to use this drug again since the law was effective?

A. No, I haven't." (171a-172a)

forced to resume because there were no adequate substitutes. (J.S. 6a) George Patient, a post-operative cancer patient, went out of state to find the Schedule II drug he had used before the filing requirement existed when substitutes failed to help him mitigate pain. (J.S. 6a)

Four doctors testified that they felt compelled to inform patients of the listing and computerization of their names. The Court noted in its opinion that these doctors had all reported

> "a reaction of shock, fear and concern on the part of their patients on learning that their names would be sent to Albany and put on a computer." (J.S. 7a)*

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*One doctor testified to patient reactions to the filing requirement and to its interference with required medical treatment:

A. "Most of them are shocked, hurt. Some of them refuse the drugs and in some patients, the schizophrenics, we are reluctant to even advise the drugs because they are suspicious enough to begin with, and they get involved with this and they worsen the condition, and we try to avoid the use of these drugs in those particular patients...
Q. Now, you said that in certain cases, you have decided not to use the drugs because of the filing requirements?
A. Yes.
Q. And what cases are those, mainly?

(footnote cont'd on next page)

One doctor testified that he had a substantial number of patients who as a result of the system were refusing to take Schedule II drugs despite the fact that they were medically indicated. (181a) A second doctor testified that he refused to prescribe the drug in his private practice involving pre and post-operative cancer patients. (205a)

C. No Demonstration of State Need

The District Court recognized the substantial state interest in drug regulation:

A. Mainly the schizo-affected disorders who are prone to suspicion and to have me act as a putative arm of the Government in a situation like that provokes all kinds of anxiety, even delusions, and if we can avoid the use of drugs in that situation, we try to.
Q. And so those are situations where you found the drug was medically indicated but because of the filing requirements you didn't use the drug?
A. Yes, sir." (154a-155a)

> "The state seeks to deal with a well-recognized and prevalent evil -- the widespread proliferation of drug abuse. In seeking through the legislation before us to prevent the diversion of Schedule II drugs to illegal use, the state manifestly is performing a legitimate governmental function." (J.S. 7a)

The Court stressed its reluctance to interfere with that function. But based upon a showing that the inclusion of name on the centrally filed form provided the state with no useful information, the Court found that the regulation requiring the patient's name was needlessly broad. (J.S. 11a)

The lower Court found that the only purpose served by the inclusion of the patient's name was the identification and investigation of those receiving drugs from more than one doctor or those receiving more than a 30-day supply of drugs in that period.*

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*The Court stated:

> "Indeed, admittedly the only purpose this information [patient's name] serves is to identify individual patients who without using an alias go from doctor to doctor to secure Schedule II drugs and those individuals who secure more than a 30-day supply in any single month...Overprescribing or dispensing, forgeries and thefts can be detected. Having the name of the person receiving the drugs on the state's form adds nothing." (J.S. 11a)

It was stipulated at the time of trial, twenty months after the filing requirement took effect, that only two such names had been discovered and both had been investigated. The Court found that "one investigation revealed a bona fide patient relationship. The other was still pending." (98a)

The Court, balancing the harm done to patients by the system requiring the filing of 2,000,000 prescriptions over 20 months with the meager results of that system, concluded that the comprehensive statutory scheme implementing regulations designed to control and monitor the quantities distributed was not aided by the inclusion of patient name.

> "The diminution of a constitutionally guaranteed freedom is too great a price to pay for such a small governmental yield." (J.S. 11a)

D. Leakage.

The Court did not reach the question of the security of the state's computer system, but the plaintiffs presented uncontradicted testimony of a computer expert that personnel checks were inadequate (334a), the turnover in temporary help was dangerous (334a), the physical security of the building nonexistent (338a), and the data security system unsophisticated. (341a-342a)

The state's only response to the plaintiffs' evidence about the system's lack of security was to introduce the deposition testimony of Mr. Joseph L.

Cannizaro, the director of the Bureau of Controlled Substances Licensing. Mr. Cannizaro admitted that there were no written procedures for processing printouts from the system (457a-459a), that he was unaware of the nature of employment background checks, if any, which were conducted on personnel employed by the data center (465a), that he did not know whether or not any personnel had criminal records (466a-469a), that of the 17 employees in the State Bureau "We may have five or six, possibly seven new ones," within the past year (471a), and that he did not know the background of temporary employees, the employment testing or processing for selecting them, or whether they had criminal records or not. (484a-486a)

In conclusion, the three-judge Court found that the state had not shown a need for the inclusion of patient names on the centrally filed prescription in view of the existence of detailed and extensive alternative regulations, that there was substantial injury caused to patients, and without reaching the question of security of the system, concluded that the gain to the state was not sufficient to justify the loss to the individual.

SUMMARY OF ARGUMENT

The trial Court's ruling is a narrow one which restricted one provision of the statutory scheme which was held to interfere with the individual's anonymity and the individual's right to medical care without scrutiny of the state. The Court left intact broad, comprehensive regulations.

This holding resulted from factual conclusions that:

a) this sweeping regulation, requiring the filing of 100,000 prescriptions a month, had caused a change in legitimate medically indicated treatment, had created real, harmful patient fears;

b) the state was able to achieve its legislative goals of reducing over-prescribing and detecting forged prescriptions without the inclusion of name on the form sent to the state;

c) the inclusion of name added nothing to the state program.

The doctor-patient relationship and the patient's expectations of anonymity fall well within the scope of the constitutionally protected right to privacy as defined by this Court. Roe v. Wade, 410 U.S. 113 (1973); Doe v. Bolton, 410 U.S. 179 (1973); Planned Parenthood v. Danforth, 44 L.W. 5197 (1976)

The recent cases of this Court relied upon by Appellant, Fisher v. U.S., U.S. , 96 S.Ct. 1569 (1976) U.S. v. Miller U.S. , 96 S.Ct. 1619 (1976) involve facts in which either the right of privacy was recognized, but found outweighed by a compelling state interest or matters dealing with financial papers not within the protected zone of privacy. They are easily distinguished from this case in which the interest to be protected involves intimate and personal concerns of medical care and

treatment and the right to confidentiality in the physician-patient relationship.

This Court should apply a standard of strict scrutiny, long established and reaffirmed in Danforth, supra, to the present facts. However, no matter what standard of review is applied, the state's requirement of the centralized filing of patient names cannot be upheld. The facts presented at trial show that the statute creates injury to patients while not aiding the state to achieve its intended purposes.

ARGUMENT

I

THE DISTRICT COURT HOLDING IS A NARROW ONE FOUNDED ON THE FACTS OF STATE INTERFERENCE WITH THE DOCTOR-PATIENT RELATIONSHIP AND WITH THE LEGITIMATE EXPECTATION OF PATIENT ANONYMITY, TOGETHER WITH A FINDING THAT THE REQUIREMENT DID NOT AID THE STATE IN ACHIEVING ITS PURPOSES.

In reviewing the District Court holding it is essential to focus precisely upon what the Court did and did not do.

Most importantly, the decision below was reached only after trial. The thrust of the holding was not a broad one striking down an entire statutory scheme but a narrow ruling based on the facts in the record at trial and directed toward one specific abuse within the statutory scheme. The Court had declined to enter into broad rulings of law and left intact the legislative scheme almost in its entirety.*

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* Schedule II drugs will still be prescribed only on triplicate forms issued by the Health Department. The form will still have to be purchased from the state, be numbered and be recorded as having been sold to that doctor. A copy of the form, with

(footnote cont'd on next page)

The holding did not restrict the state's ability to license the manufacture and distribution of controlled substances. §3310 et seq. It does not narrow state supervision of research. §3324 et seq. It does not reject the state classification of drugs. § 3306. It does not prohibit the use of "an official New York prescription" §3332 and §3333. It does not question the requirement that the doctor, pharmacist, and state keep the prescriptions for five years. §§3332, 3333, 3370.

Similarly the holding does not prevent the filing of the names of persons centrally in programs in which the state shows a function for that filing. (Vital statistics, for example.) The holding does not prohibit oversight by the state of the doctor-patient relationship where the method used can achieve a legitimate state purpose. The opinion leaves the state free to have the most thorough and intense regulation of drugs imaginable including the use of codes and numbers, doctor reporting and so forth as long as the state refrains from collecting and computerizing the

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the patient name, will be kept by the doctor and the pharmacist for a five-year period. The form will be forwarded to Albany with information as to the drug prescribed, the daily dosage and frequency of use and the doctor prescribing. The state can trace the prescription both to the doctor and pharmacy, can quickly review the prescribing practices of each doctor, his reliance upon particular drugs and the quantities of drugs used.

names of all patients receiving Schedule II drugs.

The holding is based on facts found at trial: (1) harm to patients resulting from diminished effectiveness in and changes of treatment and fears of stigmatization; (2) a vast state system which uses a dragnet more likely to expose the names of patients seeking drugs for legitimate medically indicated use than those obtaining drugs for illicit purposes.

The trial court examined other supposed needs for the centralized filing of names, such as detecting forged prescriptions, but found that

> "Indeed, admittedly the only purpose this information serves is to identify individual patient who without using an alias go from doctor to doctor to secure Schedule II drugs and those individuals who secure more than a 30-day supply in any single month. (J.S. 11a)

The Court found that the state prescription forms are serially numbered and sold to doctors. Each doctor and pharmacist has a DEA number. Each prescription is readily identifiable. "Over-prescribing or dispensing, forgeries and thefts can be detected." (J.S. 11a) In view of this record the Court understandably concluded that the inclusion of patient names adds nothing to the state system and the infringement of patients' privacy was unjustified."

Appellant relies heavily on "facts" not presented at trial which are said to provide a rationale for the inclusion of patient name on the centrally filed prescription. The foremost of these "facts" is found in a footnote on page 9 of appellant's brief:

> "In the September 1975 printout, the last before the judgment appealed from brought use of filed prescriptions to an effective halt, 45 reports were made (in one month). These involved patients using the same name to obtain controlled drugs (Schedule II) from multiple sources (doctor-to-doctor). Included also were prescribing over 30-day supply of a drug and use of forged or stolen prescriptions."

A parsing of that footnote shows rather that appellant seeks to mislead this Court. First, there was no showing at trial that "forged or stolen prescriptions" were in any way turned up from the printout of patient names -- rather the contrary. The footnote is similarly devoid of any indication of the connection between the inclusion of patient name and the detection of forgery, nor does it indicate how many of the "45 reports" related to these categories.

Secondly, the footnote states that these "45 reports" includes "prescribing over a 30-day supply." Such prescribing

hardly raises even a presumption of illegality or irregularity.* Suppose, for example, that a doctor originally prescribed a dosage of two milligrams per day to a particular patient, and that he prescribed 60 milligrams (a 30-day supply) to that patient, and suppose that thereafter, for whatever reason, the doctor decides that a heavier dosage is necessary, and he then prescribes more. Under these circumstances, the patient receives "over a 30-day supply." How many of these reports are included among the 45?

This leaves the last category -- persons using the same name who receive drugs from more than one doctor. After 20 months and 2,000,000 prescriptions, not one single case of illegality is cited by the state. Rather the state includes in a footnote an undifferentiated number (45) of reports, lumping common lawful practices (over a 30-day supply with illegal practices (forged prescriptions) (which the inclusion of name does not detect) to justify its massive reporting system.

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* §3331(5) is the provision relating to 30-day supply:

> "No more than a thirty day supply or, pursuant to regulations of the commissioner enumerating conditions warranting specified greater supplies, no more than a three month supply of a Schedule II, III or IV substance, as determined by the directed dosage and frequency of dosage, may be dispensed by an authorized practitioner at one time."

The State of California, in its Amicus brief, also in a footnote, reports 140 investigations in 1974 and 176 in 1975. (Amicus brief p. 8) Yet it does not differentiate among the many kinds of investigations nor give any of the results. The rationale provided by Amicus is similarly misleading. Without names, they say, a doctor could prescribe for himself and use a fictitious name which would go undetected. Yet the use of a fictitious name will not be detected by the computer. The computer does not recognize fictitious names, but only those names which repeat with more than one doctor, or those names receiving more than a 30-day supply.*

The District Court twice, on the initial motion to dismiss and on the appellee's motion for a preliminary injunction, was confronted by the reasoning advanced in both the appellant's and Amicus' brief and in each instance in the preliminary

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* See testimony of Cannizzaro: (Head of State Bureau)
  Q. There is only one of these printouts which contains a patient name, is that correct?
  A. That is correct, sir...
  Q. What is the purpose of showing the patient's name on that?
  A. It identifies a patient who has received in excess of a 30-day supply of a Schedule II controlled substance, either from one or more than one practitioner. (415a)

stage found the reasoning plausible. But at trial, where the rationale was confronted in the context of the evidence, reduced to testimony and examined, the rationale failed. The inclusion of patient name on the centrally filed prescription does not reveal the use of fictitious names. Names do not reveal forgeries. In fact there is no showing that the use of a fictitious name would even trigger a response from the system.

The holding below was, thus, a narrow one compelled by the facts in the record. The Trial Court's careful conclusions resulting from that record should be sustained.

II

THE INDIVIDUAL'S NEED TO RECEIVE MEDICAL CARE AND ADVICE FROM HIS PHYSICIAN, AND HIS RIGHT TO ANONYMITY WITHIN THE DOCTOR-PATIENT RELATIONSHIP, ARE INTERESTS WHICH FALL SQUARELY WITHIN THE CONSTITUTIONALLY PROTECTED RIGHT OF PRIVACY

This case raises directly the question whether a state may systematically intrude into the physician-patient relationship by requiring the massive filing and computerization of the names of all patients who use duly prescribed legal drugs without a showing that such a requirement serves a legitimate governmental function. The challenged provision establishes, in effect, a centralized state registration of Schedule II drug users. Appellees respectfully submit that this violates their constitutional right of privacy.

Some plaintiff-appellees are patients receiving medical treatment for terminal cancer, migraine headaches or psychological conditions of differing natures. Other plaintiff-appellees are parents of children who are receiving a medically-indicated lawful drug (ritalin) to help them overcome the handicap of hyperkenisis. These appellees seek medical care and treatment

with the expectation and need to consult with their physicians in an atmosphere of confidentiality and security, with the knowledge that the decisions they make and the treatment they obtain will not automatically and systematically be scrutinized by the state government. The medical problems on which they consult their physicians are among the most intimate and personal concerns of the individual. Their subject matter falls well within the constitutionally protected zone of privacy.*

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*Justice Blackmun in Roe v. Wade, 410 U.S. 113, 153 (1973) traced the development of the broad right of privacy:

> "back perhaps as far as Union Pacific R. Co. v. Botsford, 141 U.S. 200, 251 (1891) the Court has recognized that a right of personal privacy, or a guarantee of certain areas or zones of privacy, does exist under the Constitution."

This line extends through Meyer v. Nebraska, 262 U.S. 390, 399 (1923) (education of one's children); Pierce v. Society of Sisters, 268 U.S. 510, 535 (1925) (choice of schools for children); Skinner v. Oklahoma, 316 U.S. 535, 541 (1943) (sterilization); Prince v. Massachusetts, 321 U.S. 158, 166 (1944) (education of children), to the more recent cases of Griswold v. Connecticut, 381 U.S. 479, 497 (1965) (contraception); and Roe v. Wade, 410 U.S. 113 (1973) and Doe v. Bolton, 410 U.S. 179 (1973) and more recently Planned Parenthood v. Danforth, 44 L.W. 5197 (1976).

As enunciated by this Court, the scope of the right of privacy extends to those areas of individual conduct that are most intimate and personal, and in which the individual, as a result, expects to be let alone. Medical treatment and the care of one's body clearly fall squarely within any view of intimate human concerns. Our society has always afforded confidentiality to the doctor-patient relationship.* Clearly a medical patient has always had an expectation of privacy. At trial below, the appellee-patients testified to their

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* The tradition of confidentiality extends back at least to the Hippocratic Oath:

> "Whatever, in connection with my professional practice, or not in connection with it, I see or hear, in the life of men, which ought not to be spoken abroad, I will not divulge, as reckoning that all such should be kept secret."

As quoted in "Physician's Tort Liability ... For Unauthorized Disclosure ...," 20 ALR 3d 1109, 1113.

own expectations of freedom from the intrusion of the state.* The four doctors who testified also substantiated the patients' reactions which included fear or shock, and more significantly the withdrawal from medically indicated treatment. (154a-155a, 181a, 188a)

Judge Friendly writing for the Second Circuit in this matter noted the patient's desire for privacy:

> "It is immaterial that the ailment is usually not one that should arouse any emotion toward the victim save sympathy; most people simply do not want their ailments to be generally known." (Footnote 480 F.2d at 108).

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* One parent of a child testified that he had trouble accepting that the legislation could be as it was described.

> "I protested strongly. I was very upset, which I expressed to him, [the doctor] and I told him that I had trouble accepting that the legislation would be as he described it, given the fact that the child was getting normal treatment for a known medical disorder and this was the customary treatment for it. (117a)

The right of privacy, extends to those areas of conduct where the individual expects and has reason to expect privacy. In the words of Justice Harlan:

> "My understanding of the rule... is that there is a twofold requirement, first that a person have exhibited an actual (subjective) expectation of privacy and, second, that the expectation be one that society is prepared to recognize as reasonable." Katz v. United States, 389 U.S. 347, 360 (1967) (concurring opinion).

This Court has recognized the protection of the individual's right to privacy in connection with the right to medical care and treatment and the right of the individual to receive medical advice from his physician free from state intrusion. In Eisenstadt v. Baird, 405 U.S. 348, 454 (1972) this Court recognized a right to access to contraceptive devices:

> "If the right of privacy means anything it is the right of individual, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child".

The right to seek medical care free from state intrusion was most explicitly articulated in the decisions of Doe v. Bolton, 410 U.S. 179 (1973) and Roe v. Wade, 410 U.S. 113 (1973).

In Doe, this Court spoke of "the woman's right to receive medical care in accordance with a licensed physician's best judgment and the physician's right to administer it..." (at 198).

Similarly, in Roe, Justice Blackmun spoke of the right of the doctor to administer care free of state interference:

> "The decision [in this case] vindicates the right of the physician to administer medical treatment according to his professional judgment up to the points where important state interests provide compelling justifications for intervention. Up to those points, the abortion decision in all its aspects is inherently, and primarily a medical decision, and basic responsibility for it must rest with the physician. If an individual practitioner abuses the privilege of exercising proper medical judgment, the usual remedies, judicial and intra-professional, are available." (at 165-166)

This Court reaffirmed these holdings in Planned Parenthood v. Danforth, 44 L.W. 5197 (1976). That holding should resolve any doubt that state regulations concerning medical records fall within the zone of the constitutionality protected right of privacy. There the challenge, in part, was to requirement that medical facilities and physicians compile "relevant maternal health and life data". (at 5205) There

was no requirement that any data be filed centrally. While this Court upheld the statute, it described the statute, which unquestionably was far more carefully drawn than the sweeping New York law involved here, as "perhaps approaching permissible [constitutional] limits" (at 5205). Apart from the question of the applicable standard for review, to be discussed infra, Danforth makes clear that state laws that require the compilation of the medical records of individual citizens fall well within the scope of the constitutionally protected right of privacy.

The claim of the expectation of privacy does not rest alone in the doctor-patient relationship but also on the expectation of anonymity that the citizen expects from the state in matters of personal nature. Again, this Court has been most careful to protect individual anonymity where compelled identification will tend to discourage lawful activity. Bates v. City of Little Rock, 361 U.S. 516, 522-23 (1960); NAACP v. Alabama, 357 U.S. 449, 462, (1958).

Appellant argues in his brief (pp 14-21) that there is no right of privacy in the right to receive medical care and advice from one's physician within the doctor-patient relationship, nor in the need for anonymity connected with medical treatment. For this he relies upon recent holdings of this Court. Fisher v. United States, U.S. , 96 S.Ct. 1569 (1976), United States v. Miller, , U.S. , 96 S. Ct. 1619 (1976). Yet these cases involved the use

of subpoenas to enforce criminal statutes, where the interests of the state were demonstrably compelling and the scope of the required production was narrow. In each case the government sought financial records of an individual it suspected of criminal tax violation.*

Indeed, the reliance upon Fisher is totally misplaced. There this Court upheld an Internal Revenue Service summons of records relating to a taxpayer which were in the physical possession of the taxpayer's lawyer. Contrary to appellant's contention, Justice White, writing for the Court, did not reject the contention that an individual's privacy was involved but rather stated:

> "...the Court has never suggested that every invasion of privacy violated the privilege."[against self incrimination] (at 1575)

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* The recent holding in Andresen v. Maryland, 44 L.W. 5125 (1976) similarly involves the enforcement of a criminal statute, in that case by search warrant. The search warrant avoided any Fourth Amendment problem. The Fifth Amendment protection of privacy was recognized but was not violated as the state need was compelling. (at 5129, 5130, relying upon Fisher, supra).

Similarly, Justice Brennan, in his concurrence, pointed out that the Fifth Amendment cases relied upon by the majority which permit an invasion of privacy to so not because privacy is not involved but because the right of privacy is not absolute (at 1584). In Fisher, the enforcement basis for sustaining the subpoena.*

Appellant also relies on Association of American Physicians & Surgeons v. Weinberger, 395 F. Supp. 125 (N.D. Ill. 1975), affd sub nom. Association of Physicians & Surgeons v. Matthews, U.S. , 46 L. Ed.2d 229, 96 S.Ct. 388, upholding regulations permitting review of medical treatment records prior to federal payment for services. The challenge was to the statute on its face, with no record of injury to anyone including patients. The District

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* Fisher would indeed have been analogous to the present case if all attorneys were requested to file client's names, addresses and levels of income (with appropriate corresponding papers) for all clients having income above $30,000. The sweep of such regulation would surely raise not only an issue of the right to privacy, but presumably would be found to be an excessive intrusion into personal liberty.

Court did not hold in that matter that there was no right of privacy, as appellant implies (Brief, pp. 19-20). Rather, the Court found that the right gave way to a legitimate (and obvious) state purpose, protecting the public purse. In fact, the Court noted that the federal statute

> "provides that reporting procedures should utilize to the greatest extent possible 'methods of coding which will provide maximum confidentiality as to patient identity and assure objective evaluation consistent with the purposes of this part.' 42 U.S.C. §1320C-4" (at 135)

The holding in Kelley v. Johnson, U.S. , 96 S.Ct. 1440 (1976), also cited by appellant (Brief p. 19), in which this Court upheld a county regulation governing the hair grooming of policemen, similarly is not applicable here. The expectation of privacy connected with the right of a policeman to have hair of any length is limited indeed. Citizens and policemen expect supervision of dress and appearance for public employees. Patients, however, expect privacy when visiting a doctor.

These plaintiffs were not engaged in business, nor were they the subject of a criminal investigation. They are not trying to suppress financial documents relating to business activities where the state had probable cause to believe a crime was committed. Nor are they public employees.

These are medical patients - a post-operative cancer patient, a patient suffering from encephalitis, and parents of children receiving a drug to increase their attention span. These are persons who are seeking treatment for physical and psychological disorders. These patients are confronted by a sweeping state requirement compelling the massive centralized filing of the names of hundreds of thousands of patients per year.

Appellees submit that this systematic intrusion into the physician-patient relationship unquestionably implicates their constitutionally protected right of privacy as enunciated by this Court.

III

BY WHATEVER STANDARD OF REVIEW THE REQUIREMENT OF CENTRALIZED FILING OF PATIENTS' NAMES FAILS TO FULFILL ANY STATE PURPOSE, IS OVERBROAD AND UNREASONABLE AND CANNOT BE SUSTAINED

Appellees recognize that the right of privacy is not absolute. Once the right has been found to apply, the Court must review the requirement which intrudes upon the right to determine if the intrusion is justified.

The appellees urge a standard of strict scrutiny to review of this statute. This is the standard affirmed by this Court in Roe v. Wade, 410 U.S. 113 (1973) and reaffirmed in Planned Parenthood v. Danforth, 44 L.W. 5197 (1976)*.

*See Roe v. Wade, 410 U.S. 113, 155:
"Where certain 'fundamental rights' are involved, the Court has held that regulation limiting these rights may be justified only by a 'compelling state interest,' Kramer v. Union Free School District, 395 U.S. 621, 627, 89 S.Ct. 1886, 1890, 23 L.Ed2d 583 (1969); Shapiro v. Thompson, 394 U.S. 618, 634, 89 S.Ct. 1322, 1331, 22 L.Ed.2d 600 (1969); Sherbert v. Verner, 374 U.S.

(footnote cont'd on next page)

There can be no doubt that in applying this standard to the New York statute it cannot be sustained. First, the statute has created significant injury to patients, fear, and resulting change of medical treatment cited throughout this brief.* This burden placed upon the right to treatment is the element of injury which this Court, per Justice Blackmun, found lacking in Planned Parenthood v. Danforth, 44 L.W. 5197, 5206 (1976) where the Court sustained the record-keeping requirement.

398, 406, 83 S.Ct. 1790, 1795, 10 L.Ed. 2d 965 (1963), narrowly drawn to express only the legitimate state interests at stake. Griswold v. Connecticut, 381 U.S., at 485, 85 S.Ct., at 1682; Aptheker v. Secretary of State, 378 U.S. 500, 508, 84 S.Ct. 1659, 1664, 12 L.Ed. 2d 992 (1964); Cantwell v. Connecticut, 310 U.S. 296, 307-308, see Eisenstadt v. Baird, 405 U.S., at 460, 463-464, 92 S.Ct., at 1042, 1043-1044 (White, J., concurring in result)."

*This brief has not dealt directly with the issue of plaintiff-appellees' standing. In part this is because the other appellees' brief does so. But, more importantly, the issue of standing is settled by the fact of clear injury to the plaintiffs as testified to by the patients at trial. Testimony showed altered medical treatment, children withdrawn from medically indicated drugs. By the standards of this Court in Baker v. Carr, 369 U.S. 186 (1962).

(footnote cont'd on next page)

The Missouri statute was found to have resulted in "no legally significant impact or consequence on the abortion decision or

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these plaintiff-appellees are persons who have a personal stake in the outcome sufficient to assure a sharpened presentation of the issue.

The doctor-plaintiffs would similarly appear to fall well within the standing standard of Singleton v. Wulff, 44 L.W. 5213 (1976). One doctor testified that he had given up prescribing Schedule II drugs (205a). The others all stated that the requirement affected their practice. These doctors have a financial stake in the outcome, and as in Wulff, they may be permitted to assert their patients' right of privacy.

In fact Judge Friendly in his opinion in this case had little trouble with the standing issue even for the physicians: "The standing of the physicians seems to be established by Griswold v. Connecticut, 381 U.S. 479 (1965) and Doe v. Bolton, 410 U.S. 179 (1973)"480 F.2d at 107 (Footnote).

These plaintiffs are not like those in Laird v. Tatum, 408 U.S. 1, 13-14 (1972) (cited by appellant at 46). Those plaintiffs did not change their circumstances, nor suffer injury of any kind. The patient-plaintiffs have standing because they are (without choice) involved in a relationship with their doctor upon which the challenged regulation intrudes directly. Their names and a record of their treatment are forwarded to the State Department of Health. They are directly subject to the state statute.

on the physician-patient relationship." (5206) Furthermore, the Missouri statute in Danforth required no centralized reporting, the most intrusive element of the statute here. The Missouri statute was also found to be "reasonably directed to the preservation of maternal health...," (at 5205) unlike the provision here. Even so Justice Blackmun found that the regulation "perhaps" approached "permissible limits." With these three factors - burden on the relationship, centralized filing, and no connection to patient health - the New York statute goes clearly beyond permissible constitutional limits.

Furthermore, the requirement of patient name is not narrowly drawn to achieve only the intended purpose without offending the individual's right. The statute, as left intact by the decision of the three-judge Court, requires both the doctor and the pharmacist to maintain copies of the prescription with the patient name for 5 years. (PHL §§3332, 3333). The third copy sent to the state could easily substitute a coded number for the patient's name.*

*Parallel Federal law, 21 U.S.C. §829, which provides explicitly for "Schedule II" prescriptions, and which requires that all such drugs be dispensed by written prescription, does not require the centralized filing of prescriptions.

Furthermore, while the three-judge Court did not reach the issue of security, there is no doubt that the filing and processing of more than 1 million prescriptions per year into a computerized system poses a danger to every person named. (Can it be doubted that athletes, celebrities, politicians and perhaps even judges may well be tempted to substitute other's names to avoid identification?*) Although security problems are self-evident, the record shows that the head of the enforcement branch of the Department was unaware of the nature of employment checks (465a), did not know whether employees had criminal records (466a-469a) and admitted to having "possibly" seven new employees in the past year out of a total of 17 (471a). The check on temporary help was even more uncertain (481a-486a).

Appellant argued below that the present system of massive systematic centralized filing imposed no greater burden on the doctor-patient relationship than existed under the previous system which is involved under the no centralized filing of prescriptions whatever. The Court below rejected that argument forthrightly:

> "The intrusion here is not only more immediate, its impact is greater." (J.S. 12a)

*Appellant's brief notes that physicians have filled out the forms under team names to avoid athlete identification. (Appellant's brief, p. 30).

The testimony of patients as to their fear is evidence of this. The recent history of governmental abuse connected with wire-taps and break-ins do not reassure citizens that their records are in safe hands, particularly where by pushing a single button the state can quickly compile a personal drug record. The seriousness of the intrusion is found in the testimony of one doctor who testified that with certain patients he had stopped prescribing Schedule II drugs because of the filing requirement.*

However, appellees do not rely upon a standard of strict scrutiny. Whatever the standard of review, even a rational basis test,** this massive cataloguing of patient names does not meet constitutional standards. The findings of fact of the Court below summarized in Section I of the argument show injury to patients and no gain whatever to the state from the inclusion of name on the centrally filed form. Those seeking drugs for illicit

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*He testified:

> "Mainly the schizo-affected disorders who are prone to suspicion and to have one act as a putative arm of the government in a situation like that provokes all kinds of anxiety, even delusions, and if we can avoid the use of drugs in that situation, we try to." (155a)

**Urged upon this Court by Appellant. (Brief p. 22) McGowan v. Maryland, 366 U.S. 420.

purposes can easily circumvent the system by the use of false names. Forgeries and stolen prescriptions are revealed not by reference to names but by tracing prescription numbers and matching them with reports submitted by doctors. As summarized by the three-judge Court, after trial:

> "The state prescription form program provides for issuing serially numbered prescription forms to physicians. Each doctor prescribing and each pharmacist dispensing any Schedule II drugs are given a DEA number. They, therefore, are readily identifiable. The state can promptly determine the quantity of drugs prescribed and dispensed by particular physicians and pharmacists. Over-prescribing or dispensing, forgeries and thefts can be detected. Having the name of the person receiving the drugs on the state's form adds nothing." (JS 11a)

Where the inclusion of name adds nothing it is irrational and offensive to permit the vast compilation of patient names in a state computer. It is also constitutionally impermissible.*

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*The appellant is unable to cite a single instance of illegal drug distribution or use revealed by the existence of patients' names on the centrally filed prescription. The requirement, then, appears premised on the conjecture that it may have occasional investigative utility. (Appellant's

(footnote cont'd on next page)

However, appellees urge that this area of intimate human activity - the doctor-patient relationship and the need for medical

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brief p. 30 points to one example where information could be sought through use of the centralized information.) Appellees do not deny that if citizens were required to report all activity to government prior to engaging in it, government could better account for activity, criminal and non-criminal. But such surveillance is incompatible with our "concept of ordered liberty." Palko v. Connecticut, 302 U.S. 319, 325 (1937). Efficiency is not a value which overrides the interest in personal liberty. As stated by Justice White in Stanley v. Illinois, 405 U.S. 645, 657 (1972), favorably cited in Cleveland Board of Education v. La Fleur, 414 U.S. 632, 648 (1974):

> "The establishment of prompt efficacious procedures to achieve legitimate state ends is a proper state interest worthy of cognizance in constitutional adjudication. But the Constitution recognizes higher values than speed and efficiency. Indeed, one might fairly say of the Bill of Rights in general, and the Due Process Clause in particular, that they were designed to protect the fragile values of a vulnerable citizenry from the overbearing concern for efficiency and efficacy

(footnote cont'd. on next page)

treatment - necessitates a more demanding review than the test of mere rational basis. In the past this Court has applied standards more strict than mere rationality yet less precise than strict scrutiny.* As Justice Marshall suggested in his dissent in San Antonio Independent School District v. Rodriguez, 411 U.S. 1(1973), in the context of equal protection analysis, there appears to have been a spectrum of levels of scrutiny:

> "A principled reading of what this Court has done reveals that it has applied a spectrum of standards in reviewing discrimination allegedly violative of the Equal protection Clause. This spectrum clearly comprehends variations in the degree of care with which the Court will scrutinize particular classifications depending, I believe, on the constitutional and societal importance of interests adversely affected and the recognized invidiousness of the basis upon which the particular classification is drawn." (at 99)

> that may characterize praiseworthy government officials no less, and perhaps more, than mediocre ones."

This cumbersome system would hardly be termed efficient since as it has produced no yield. However, appellant's argument that it may result in some greater efficiency does not establish its constitutionality.

*CF discussion of middle level scrutiny, Comments, Constitutional Law, The Right To Privacy, 50 N.Y.U.L. Rev. 1149 (1976).

Justice Harlan, in his dissent in Shapiro v. Thompson, 394 U.S. 618 (1969), where the majority applied the strict scrutiny test, developed a balancing test. Finding that "the right to travel interstate is a 'fundamental' right" (394 U.S. at 671) having its source in the due process clause, and finding also a strong state interest in preventing welfare fraud (at 673), he continued:

> "The next question is the decisive one: Whether the governmental interests served by residence requirement outweigh the burden imposed upon the right to travel."

Similarly, a test of "careful scrutiny" was applied by the three-judge Court in Population Srvs. Int'l v. Wilson, 398 F.Supp. 321, (S.D.N.Y. 1975) appeal pending sub non Carey v. Population Services Int'l. 44 U.S. L.W. 3162, to the question of a state statute limiting a minor's access to contraceptives:

> "The Due Process Clause requires therefore, that the Court carefully scrutinize each provision of the statute to determine whether, as drafted, it is in fact sufficiently related to a state interest to justify its infringement of the right at stake." (at 331)

The Court assumed the state's right to regulate the morality of minors, but found no showing that the policy actually promoted that interest and found evidence of substantial harm from the policy. As a result, the statute was found unconstitutional.

The decision of this Court in Danforth, supra, concerning records further indicates a spectrum of review. The Court sustained recordkeeping even in the first trimester. In the words of Justice Blackmun, "Recordkeeping of this kind, if not abused or overdone, can be useful to the state's interest..." (at 5205). These records fell within "permissible limits."

Appellees then do not rely on the application of strict scrutiny. They do urge that the application of a standard of mere rationality to the question of individual liberty, the need for individual autonomy and anonymity in the doctor-patient relationship, would have a damaging impact on fundamental rights. Such a step would open the door to frightening intrusion by ever more subtle state surveillance. This Court can -- as the three-judge Court did here -- allow the state to seek its legitimate interest, but must allow trial courts to be vigilant to see that the means used have the precision of a scalpel rather than an axe. Where individual liberty is involved, vigilance is always necessary and "precision of regulation must be the touchstone." NAACP v. Button, 371 U.S. 415, 438 (1963). Here precision was lacking and the three-judge Court carefully narrowed the statute.

CONCLUSION

For the foregoing reasons, the judgment below should be affirmed.

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Service of the within and receipt of a copy thereof is hereby admitted this ..... day of May, A.D. 1976.

Supreme Court, U. S.
FILED
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IN THE

Supreme Court of the United States

October Term, 1975
No. 75-839

ROBERT P. WHALEN, as Commissioner of Health of the State of New York,

Appellant,

vs.

RICHARD ROE, an infant, by ROBERT ROE, his parent; JOHN DOE, an infant, by MARY DOE, his parent; JAMES MOE, an infant, by MICHAEL MOE, his parent; JANE POE, MATTHEW T. BRODY ISRAEL L. SCHMIERER and EMPIRE STATE PHYSICIANS GUILD, INC.,

Appellees,

GEORGE PATIENT, MARTHA PATIENT, GERALD L. LUSTIG and THE AMERICAN FEDERATION OF PHYSICIANS and DENTISTS,

Intervenor-Appellees.

On Appeal From the United States District Court for the Southern District of New York

BRIEF OF AMICUS CURIAE STATE OF CALIFORNIA

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IN THE

Supreme Court of the United States

October Term, 1975
No. 75-839

ROBERT P. WHALEN, as Commissioner of Health of the State of New York,

Appellant,

vs.

RICHARD ROE, an infant, by ROBERT ROE, his parent; JOHN DOE, an infant, by MARY DOE, his parent; JAMES MOE, an infant, by MICHAEL MOE, his parent; JANE POE, MATTHEW T. BRODY, ISRAEL L. SCHMIERER and EMPIRE STATE PHYSICIANS GUILD, INC.,

Appellees,

GEORGE PATIENT, MARTHA PATIENT, GERALD L. LUSTIG and THE AMERICAN FEDERATION OF PHYSICIANS and DENTISTS,

Intervenor-Appellees.

On Appeal From the United States District Court for the Southern District of New York

BRIEF OF AMICUS CURIAE STATE OF CALIFORNIA

Interest of Amicus Curiae

In this civil rights case a three-judge panel of the United States District Court for the Southern District of New York declared unconstitutional as a violation of the right of privacy the provisions of the New York Public Health Law, McKinney's Consol. Laws, c. 45, §3300 *et seq.*, which require the inclusion of patients' names and addresses on copies of Schedule

II drug prescriptions which are filed with the state and retained for a short period in a confidential, computerized data bank. In overturning the statute the district court characterized as coming within the fundamental constitutional right of privacy the interest of plaintiff patients in maintaining secrecy as to the nature of their physical condition and medical treatment. The court further held that plaintiff physicians and patients possess a right of privacy as to their confidential communications in the physician-patient relationship and that the physician-patient relationship also encompasses the right of physicians to administer treatment and the right of patients to receive treatment.

Notwithstanding the statutory restrictions on access to the data compiled by the state narcotics bureau and the confidential status of the information there maintained, the district court held that so much of the Public Health Law as requires the reporting to state authorities in Albany of the names and addresses of the patients who receive Schedule II drugs violates the right of patients to confidentiality as to their medical condition and treatment. In addition, the court held the fear of patients that information regarding their legal use of Schedule II drugs might possibly be disclosed and then misinterpreted by third parties had in fact caused some patients to refuse treatment using Schedule II drugs, and that their own refusal of such treatment constituted a violation of their rights and the rights of their physicians to the right of privacy embodied in the physician-patient relationship.

In the State of California, prescription reporting requirements similar to those contained in the challenged New York statute have been adopted as part of California's continuing effort to combat the serious problems of drug abuse among its citizenry and illicit drug trafficking within the State. The common interest of California and its sister state of New York in a strong program against drug abuse and a fair regulatory scheme for the legal use of Schedule II drugs brings the State of California before this Honorable Court as *amicus curiae*.

Summary of Argument

The regulation of the use of Schedule II drugs comes well within a State's broad police powers to promote the health and welfare of its citizenry. New York Public Health Law, McKinney's Consol. Laws, c. 45, §3300 *et seq.*, which embodies a triplicate prescription requirement for Schedule II drugs, sets forth a reasonable and fair regulatory scheme for those drugs which have some important medical uses but which also have a high potential for abuse. The State's interest in discouraging and controlling the illicit prescription of Schedule II drugs as well as its interest in preventing patients from securing unlawful quantities of drugs by seeking prescriptions from a number of physicians justifies the reporting requirement of section 3331(6).

The inclusion of a patient's name and address on a prescription is useful to detect persons who go from doctor to doctor for separate prescriptions of Schedule II drugs which in the aggregate constitute an unlawful amount. The inclusion of the patient's identity is also useful for detecting the issuance by unscrupulous physicians of unlawful multiple prescriptions to a single patient. While the new triplicate reporting requirement may not, in its infancy, have resulted in large numbers of criminal prosecutions, the statute is nonetheless effec-

tive as a deterrent against abuse and illegal distribution of Schedule II drugs.

The reporting requirement for Schedule II drugs does not violate the right of privacy of plaintiffs. The court below erroneously held that a fundamental right of privacy protects the right of plaintiff patients to secrecy as to their medical condition or treatment. While the right to privacy is not easily defined, for constitutional purposes the right is limited, except where related to other articulable protected rights, to the most basic aspects of the human condition such as the right to marry a person of any race or the right to an abortion. The right to the secrecy of one's medical treatment simply does not involve a fundamental issue of the human condition. Since the right is not fundamental, a regulatory scheme which marginally infringes on the right need not be supported by a compelling state interest. Moreover, since the New York prescription reporting requirement provides for the confidentiality of the reported information, the interest of patients in secrecy is substantially maintained.

ARGUMENT

I

The Statutory Requirement That Prescriptions for Schedule II Drugs Be Issued in Triplicate Serves a Legitimate Function in the States' Efforts to Control Trafficking in Illicit Drugs

The three-judge panel below declared unconstitutional provisions in the New York Public Health Law which established the regulation that prescriptions of Schedule II drugs be written in triplicate with one copy sent to the State Bureau of Controlled Substances, Licensing and Evaluation (BCSLE). The court held that the specific requirement that patients' names be included in the copies of prescriptions filed with BCSLE served no substantial state purpose and that the requirement violated the patients' right of privacy manifested both in the patients' right to secrecy as to their medical condition or treatment and the rights of doctors and patients in the physician-patient relationship.

The State of California, *amicus curiae* on behalf of appellant herein, submits that New York's Public Health Law, like its California counterpart Uniform Controlled Substances Act, constitutes a vital component of the state's effort to combat drug abuse and that the public interest served by these statutes far outweighs any interest of plaintiffs to be free from its regulatory scheme.

It is an established principle that a state has broad power to establish and enforce standards of conduct within its borders relative to the health of its citizens. This authority is a vital part of a state's police power. *Barsky v. Board of Regents*, 347 U.S. 442, 449 (1954). Included in the police power is the right of the state to regulate the administration of drugs and to over-

see all professions concerned with health. *Robinson v. California,* 370 U.S. 660, 664 (1961); *Barsky v. Board of Regents, supra; Mugler v. Kansas,* 123 U.S. 623, 661 (1887).

In 1972, California[1] adopted in substance the Uniform Controlled Substance Act. Cal. Stats. 1972, c. 1407, p. 2987, §2; Cal. Health & Saf. Code §§11000-11651. This act was designed by the National Conference of Commissioners on Uniform State Laws to supplant the Uniform Narcotic Act (see 19 U.L.A. at p. 146) and to achieve uniformity among the laws of the states and the federal government. 21 U.S.C. §801 *et seq.*

Included in this act are special provisions for the prescribing of Schedule II drugs which are those drugs having accepted medical uses but also a high potential for abuse, which abuse may lead to severe psychic or physical dependence. Cal. Health & Saf. Code §11165; Uniform Controlled Substances Act, 9 U.L.A. §205; 21 U.S.C. §812(b)(2).

The basic general objective of the controlled substances laws is to provide a regulatory system which will permit the legal use of controlled substances and which will at the same time prevent and punish illegal use. Uniform Narcotic Act, 9 U.L.A. p. 523 (Prefatory Note). Because Schedule II drugs have a high potential for abuse, such drugs are subjected to special triplicate reporting requirements. 21 U.S.C. §801; Exec. Order No. 11599, 36 F.R. 11793.

The triplicate reporting requirements are not of recent origin in either California law (Cal. Stats. 1939,

[1]Along with California and New York, Idaho and Illinois have similar provisions. Idaho Code §37-2723 *et seq.;* (Ill.) S.H.A., c. 56½, §1309 *et seq.*

1097, former Cal. Health & Saf. Code §§11166.06, 11166.11) or in New York law (McKinney's Consol. Law, c. 45, §3300 *et seq.*)

The name and quantity of the controlled substance, the direction for use, the name and address of the prescriber and the federal controlled substances registration number have long been required to be on the triplicate prescription blank. *See* Cal. Health & Saf. Code §11150. Plaintiffs in this case concede that the states have a substantial and legitimate interest in keeping records of the above information for the purpose of preventing the diversion of Schedule II drugs to illegal use. The maintenance of such records by the states is conceded to be within the police power.

Plaintiffs contend, and the three-judge panel below found, however, that the required reporting of patients' names and addresses did not have a legitimate purpose. There is a suggestion by the three-judge court, moreover, that the name of the patient could be deleted from the forms without any loss in effectiveness of the program. *Roe v. Ingraham,* 403 F.Supp. 931, 937 (S.D.N.Y. 1975).

The court held that the sole purpose served by the inclusion of patients' names was to discover incidents of patients going from doctor to doctor in order to secure an oversupply of drugs. In so holding, the court noted that only one incident of unlawful physician shopping had been uncovered during the short life of the statute.[2]

[2]The California State Triplicate System processed 567,505 prescriptions in 1974, and 593,236 prescriptions in 1975. From

(This footnote is continued on next page)

Amicus submits that the court's holdings below are drastically in error. It is true that the primary purpose for the inclusion of patients' names on the triplicate prescription form is to identify the patient who, without using an alias, goes from doctor to doctor to obtain Schedule II narcotic drugs. *See Roe v. Ingraham, supra.* This, however, is not the only purpose of requiring patients' names. For example, a patient without using an alias could go from doctor to doctor to obtain Schedule II drugs. If the patient's name was not required to be written, a physician could write Schedule II prescriptions using several blanks for the same patient for a total amount in excess of generally accepted usage. Detection of such activity would be very difficult. Also, the physician might be less concerned with the status of his patient and perhaps be motivated by monetary gain if his prescribing habits were scrutinized only for proper dosage, dosage schedule and amount. *See* Cal. Health & Saf. Code §11156 (prohibition of prescribing controlled substances to an addict or habitual user). The physician could prescribe Schedule II drugs for himself by using fictitious names and the violation would remain undetected. *See* Cal. Health & Saf. Code §11170 (no person shall prescribe a controlled substance for himself). If the patient's name is not required, the greatest danger would occur when the pharmacist and the physician conspire to issue and fill Schedule II prescriptions using fictitious names thereby divert Schedule II drugs from legal channels to the more profitable illicit market.

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these were generated 140 investigations in 1974, and 176 investigations in 1975. These figures indicate quite clearly the efficacy of the system, not only in early detection of violations, but also as a strong control in preventing the diversion of licit drugs to illegitimate channels.

These are but a few examples illustrative of the important part that the inclusion of patients' names in prescription forms plays in regulating the prescription of Schedule II drugs.

Amicus submits, moreover, that the three-judge panel below placed undue emphasis on the fact that only one incident of physician shopping was uncovered in New York between the enactment of the statute in question in 1972 and the time of the trial below. In fact, a primary purpose of the statute was to ensure that doctors would exercise care in prescribing Schedule II drugs and to discourage both the excessive prescribing of such drugs by doctors and unlawful shopping for physicians by patients. The fact that few prosecutions are brought under the statute may very well be a reflection of its effectiveness as a deterrent.

There can be no question that the inclusion of patients' names in the triplicate prescription forms for Schedule II drugs has at least the potential for deterring the unlawful dispensation and consumption of dangerous drugs. Given the severity of the drug abuse problem in the United States and further given the vital interest of the states in combatting the problem and in promoting the health of their citizens under the police power, the range of valid choices which the states may make in this area must necessarily be very broad. The wisdom of any particular choice within the allowable spectrum was not properly a question for the three-judge panel below. *See Robinson v. California,* 370 U.S. 660, 666 (1961).

II

The Schedule II Drug Legislation Does Not Unconstitutionally Interfere With the Physician-Patient Relationship

Plaintiffs claim that the Schedule II drug legislation unconstitutionally interferes with their right of privacy as embodied in the physician-patient relationship. *Amicus* respectfully submits that the physician-patient relationship is not by itself within the zone of privacy that is accorded constitutional protection.

The right of privacy is an amorphous right and is not found in any specific guarantee of the Constitution. It has been recognized in some cases to be implicit in the specific amendments to the Constitution: *i.e.*, the First Amendment, *Stanley v. Georgia*, 394 U.S. 557 (1969); the Fourth and Fifth Amendments, *Terry v. Ohio*, 391 U.S. 1 (1968); *Katz v. United States*, 389 U.S. 347 (1967); the Ninth Amendment, *Griswold v. Connecticut*, 381 U.S. 479 (1965) (Goldberg, J. concurring). In other cases it has been recognized as being within the penumbra of the Bill of Rights (*Griswold, supra; see* Dixon, *The Griswold Penumbra: Constitutional Charter for an Expanded Law of Privacy?*, 64 Mich. L. Rev. 197 (1965-66)), or in the concept of personal liberty guaranteed by the Fourteenth Amendments. *E.g., Meyer v. Nebraska*, 262 U.S. 390 (1923).

Except in cases where the right of privacy stems from a specific amendment to the Constitution, the right has been found to exist only in those circumstances where a substantial claim was made of infringement on an individual's freedom of choice with respect to certain basic matters as procreation, marriage, and

family life. *See Eisenstadt v. Baird*, 405 U.S. 438 (1972) (the right of a single person to obtain contraceptives); *Griswold v. Connecticut, supra* (the right of married couples to use contraceptives); *Loving v. Virginia*, 388 U.S. 1 (1967) (the right of persons of different racial classifications to marry); *Skinner v. Oklahoma*, 316 U.S. 535 (1942) (the right of a "habitual criminal" to have offspring); *Meyer v. Nebraska, supra* (the right of an individual to acquire useful knowledge); *Doe v. Bolton*, 410 U.S. 179 (1973) and *Roe v. Wade*, 410 U.S. 113 (1973) (the right to an abortion).

Plaintiffs claim and the district court agrees that the instant case falls within the purview of *Doe v. Bolton* and *Roe v. Wade* because those cases also involved the physician-patient privilege. *Amicus* submits that reliance on the abortion cases is misplaced. The fundamental question in both abortion cases was the right of a woman to decide on whether to terminate her pregnancy. In *Roe* this Court reasoned:

> "The detriment that the State would impose upon the pregnant woman by denying this choice altogether is apparent. Specific and direct harm medically diagnosable even in early pregnancy may be involved. Maternity, or additional offspring, may force upon the woman a distressful life and future. Psychological harm may be imminent. Mental and physical health may be taxed by child care. There is also the distress, for all concerned, associated with the unwanted child, and there is the problem of bringing a child into a family already unable, psychologically and otherwise, to care for it. In other cases, as in this one, the additional difficulties and continuing stigma of

unwed motherhood may be involved. All these are factors the woman and her responsible physician necessarily will consider in consultation."

Roe v. Wade, supra, 410 U.S. at 153.

Plaintiffs' claim of denial of privacy is far afield from the privacy interest protected in the area of marital relations and abortion.[3] Their claim is based not upon any challenge to the state's power to restrict their freedom of action in a sphere contended to be

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[3]With few exceptions, the right of privacy under *Roe* and *Doe* has been restricted to areas of marital privacy and family life. *See Poe v. Gerstein,* 517 F.2d 787 (5th Cir. 1975) (fundamental right to an abortion applies to minors; parental and spousal consent requirements are unconstitutional); *Doe v. Poelker,* 515 F.2d 541 (8th Cir. 1975) (city policy prohibiting all nontherapeutic abortions in its publicly owned hospitals is unconstitutional); *Wolff v. Singleton,* 508 F.2d 1211 (5th Cir. 1974); *Doe v. Rose,* 499 F.2d 1119 (10th Cir. 1974) (welfare payment restrictions for abortions of indigent mothers are unconstitutional); *Population Service International v. Wilson,* 398 F.Supp. 321 (S.D.N.Y. 1975) (minor may purchase nonprescription contraceptives); *Baird v. Bellotti,* 393 F.Supp. 847 (D. Mass. 1975) (minor may have abortion performed without consent of parents); *Baird v. Lynch,* 390 F.Supp. 740 (W.D. Wisc. 1974) (statute prohibiting sale of contraceptive devices to unmarried persons is unconstitutional); *Merrikan v. Cressman,* 364 F.Supp. 913 (E.D. Pa. 1973) (parent and child); *Roe v. Arizona Board of Regents (Arizona),* 23 Ariz. App. 477, 534 P.2d 285 (statute which provided that no abortions should be performed in a public hospital is unconstitutional); *Ponter v. Ponter (New Jersey),* 135 N.J. Super 50, 342 A.2d 574 (married woman has constitutional right to obtain a sterilization without the consent of her husband).

By contrast, numerous attempts to expand the right of privacy to other areas under the authority of *Roe* and *Doe* have consistently been rejected: *Doe v. Commonwealth's Attorney,* 75-986 decided March 29, 1976, ... U.S. .... (upholding constitutionality of law punishing voluntary homosexual acts committed by adults in their own homes); *Fitzgerald v. Porter Memorial Hospital,* 523 F.2d 716 (7th Cir. 1975) (right of marital privacy does not include the right of either spouse to have the husband present in the delivery room and the prohibition did not

private but instead on a claim that the required reporting of Schedule II prescriptions may subject them to possible injury to their personal sensibilities if the information were publicly revealed.

Plaintiffs' concern for the patients' personal and psychological sensibilities is clearly unjustified, and their concern that they will be stigmatized as narcotic and dangerous drug addicts because the state will have a file on them is unwarranted. In this society, where there is prevalent use of prescription drugs, a Schedule II drug user would hardly be considered a social outcast.

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unconstitutionally restrict the rights of physicians to practice medicine); *Spears v. Circuit Court, Ninth J.D. Warren City, Miss.,* 517 F.2d 360 (5th Cir. 1975) (state proscription of any abortion by a nonphysician is valid); *McCrary v. Runyon,* 515 F.2d 1082 (4th Cir. 1975) (a private school which holds itself out to the public has no right of privacy); *Rosenberg v. Martin,* 478 F.2d 520 (1973) (the interest in privacy of a fugitive must yield to the public interest in his apprehension); *Hill v. Sand,* 403 F.Supp. 1368 (N.D. Ill. E.D. 1975) (employee does not have right to receive personal mail at his place of employment); *Jaffess v. Secretary, Dept, of Health, Ed. and Welf.,* 393 F.Supp. 626 (S.D.N.Y. 1975) (disabled veteran who was receiving social security disability benefits as well as veteran's disability pension was not deprived of right to privacy by reason of computer comparison to locate persons who had failed to report their social security benefits); *NORML v. Guste, Jr.,* 380 F.Supp. 404 (E.D. La. 1974), *affirmed,* 511 F.2d 1400 (5th Cir. 1975) (possession of marijuana in own home is prohibited); *Blake v. State (Delaware),* 344 A.2d 260 (prostitution); *United States v. Buck (D.C.),* 342 A.2d 48 (sodomy); *State v. Baker (Hawaii),* 535 P.2d 1394 (possession of marijuana); *People v. Alexander (Michigan),* 56 Mich. App 400, 223 N.W.2d 750 (possession of marijuana); *State v. Norflett (New Jersey),* 67 N.J. 268, 337 A.2d 609 (abortion performed by a layman), *Futrell v. Ahrens* (New Mexico), 88 N.M. 284, 540 P.2d 214 (no visitation rule in dormitory); note, *Hootch v. Alaska State-Operated School System (Alaska),* 536 P.2d 793, 813, n. 19 (cultural integrity is not part of right of privacy).

Significantly, the obtainment of drugs by prescription socially legitimates its use. Moreover, the disclosure of the one ailment that may surely affect one's sensibilities, venereal disease, has always been subject to statutory reporting requirements. Cal. Health & Saf. Code §3190; *Note,* Cal. Pen. Code §11160 (reporting of injuries by deadly weapon or criminal act); Paulsen, Monroe G., *Child Abuse Reporting Laws: the Shape of the Legislation,* 67 Colum. L. Rev. (1967); *When Physician Obliged To Disclose Information Gained Through Doctor-Patient Relation,* 32 Mich. L. Rev. 1164 (1933-34); *State v. Jacobus,* 348 N.Y.S.2d 907 (1973) (reporting of certificate of fetal death, the names and addresses of parents of aborted fetuses not an invasion of privacy on women's decision to have abortion); *Town of Huntington v. N.Y. Abuse, Etc.,* 373 N.Y.S. 2d 728 (1975) (reporting requirements of participants of drug abuse program permissible). And, although these reporting requirements have not been subject to federal constitutional challenge, past precedent guides one to the conclusion that they are not violative of the Constitution. *E.g., Watson v. Maryland,* 218 U.S. 173, 179 (1910). Furthermore, in light of the limited access to and stringent control over this information, plaintiffs' fears of disclosure appear to be unreasonable.[4]

[4]The following procedures adopted in California for the use of triplicate prescription data demonstrate the high degree of security and confidentiality accorded this information.

At the end of each month copies of all official triplicate prescriptions that were filed in the month are forwarded to the Department of Justice (DOJ) in Sacramento by the pharmacies in which they were filled. These copies are transferred to IBM key punch cards by key punch operators in the department's data center. The prescriptions are then filed under an arbitrarily assigned batch number. They are retained for a period of one year from the date of issuance and are then destroyed by burning in the same fashion as confiscated drugs. During the retention period they are stored in manual metal file cabinets in the DOJ Sacramento Division of Law Enforcement Building under the same safeguards as the department's criminal record files. The building is a controlled access facility, with 24-hour guards. All personnel are admitted to their work areas by coded identification badges which include their photographs. All visitors are identified and issued badges after which they are escorted to that portion of the building which is their destination. No access is permitted to the prescription file facility.

The completed key punch cards are also stored in the same facility until the end of the month in which they are processed. They are then transported by assigned personnel to the data center computer section where they are transferred to magnetic tape. Ultimately they are destroyed by a recycling process.

The newly created tape is then run by the data center in accord with an established program to create three separate printed tabulator listings, one by prescription number, one by the doctor's federal registry number and one by the patient's last name, first initial and city of residence. These listings also indicate the prescription date, the drug type, form, dosage and quantity, as well as the previously mentioned prescription batch number. At no time does this information reside in an on-line memory. The tapes are retained under the same security as the other data center tapes for a period of 13 months.

Copies of the printed tabulators are kept at the Sacramento ILE facility and at the six area offices of the Bureau of Investigation and Narcotic Enforcement under the same security as all other confidential investigational records maintained at those offices. Their return period is one year. They are destroyed by burning.

Investigational access to the data contained in these printouts is limited by policy to state agents and, on an individual case basis, to assigned personnel of such federal and California law enforcement agencies who are working with the state agents on investigations of violations of state or federal drug laws.

Plaintiff physicians claim that their right of privacy encompasses the right of physicians to practice medicine. Their claim is based in large part on this Court's holding in *Doe v. Bolton,* 410 U.S. 179 (1973).

In *Doe*, a state criminal abortion statute requiring that two licensed physicians concur in the judgment of a pregnant woman's doctor that an abortion should be performed was held unconstitutional because the required acquiescence by co-practitioners has no rational connection with a patient's needs. It is true that this Court also noted in *Doe* that the requirement of acquiescence by co-practitioners unduly infringes on the physician's right to practice. *Doe v. Bolton, supra,* 410 U.S. at 199.

Amicus submits, however, that the right of physicians to practice medicine was not an independent ground for holding the abortion laws unconstitutional. The physician, of course, plays a vital role in the determination of whether or not a woman will terminate pregnancy. His right to practice medicine, however, rises to the level of a right of privacy only insofar as the right of the patient is affected. Unless plaintiff patients can make a showing of a violation of their right of privacy, plaintiff physicians have no independent standing to challenge the triplicate prescription requirement on the basis of the physician-patient relationship. Since plaintiff patients are not deprived of any constitutional right to treatment (see Argument, *supra*), their physicians have no independent constitutional right to administer treatment.

Plaintiffs' final claim that the prescription reporting requirement infringes upon the physician-patient privilege fails to raise a constitutional question. The evidentiary physician-patient privilege is a creature of statute and does not arise out of the Constitution. Furthermore, while it may be said that a few patients have refused to follow the advice of their doctors because of fear of public disclosure of prescribed medi-

cation, there is no evidence that free communication between patient and physician, the real object of the physician-patient privilege, has been in any way hampered by the reporting requirement of the challenged statutes.

To begin with, the relationship between a physician and his patient is not sacrosanct. In the context of rules of evidence, the physician-patient privilege is permeated with exceptions and is subject to waiver. Cal. Evid. Code §§990 *et seq.* In many jurisdictions it does not exist. Comment, *Privileged Communications,* 71 Yale L.J. 1226, 1252, n. 177 (1961). Its existence has, in fact, been criticized. Wigmore complained:

> "In only a few instances, out of the thousand daily occurring, is the fact communicated to a physician confidential in any real sense. Barring the facts of venereal disease and criminal abortion, there is hardly a fact in the categories of medicine in which the patient himself attempts to preserve any real secrecy. [Footnote omitted.] Most of one's ailments are immediately disclosed and discussed. The few that are not openly visible are at least explained to intimates. No statistical reckoning is needed to prove this. These facts are well enough known." 8 Wigmore on Evidence (McNaughton Rev. 1961), §2380a, p. 829.

The complained of disclosure does not inhibit communication between the physician and the patient. Wigmore noted:

> "Even where the disclosure to the physician is actually confidential, it would nonetheless be made though no privilege existed. People would not be deterred from seeking medical help because

of the possibility of disclosure in court. If they would, how did they fare in the generations before the privilege came? Is it noted in medical chronicles that, after the privilege was established in New York, the floodgates of patronage were let open upon the medical profession, and long-concealed ailments were then for the first time brought forth to receive the blessings of cure? And how is it today in those jurisdictions where no privilege exists—does the medical profession in two thirds of the Union enjoy, in a marked way, an afflux of confidence contrasting with the scanty revelations vouchsafed in that other third where no privilege protects? If no difference appears, then this reason for the privilege is weakened; for it is undoubted that the rule of privilege is intended [citation omitted] not to subserve the party's wish for secrecy as an end in itself but merely to provide secrecy as a means of preserving the relation in question whenever without the guarantee of secrecy the party would probably abstain from fulfilling the requirements of the relation."

8 Wigmore on Evidence (McNaughton Rev. 1961), §2380a, pp. 829-30.

In fact, the information appearing on the prescription is not protected by this privilege because it is not communication but the benefit or result of communication but the benefit or result of communication. *Id.*, §2383, p. 842.

In light of the foregoing, *amicus* submits that the physician-patient relationship claimed by plaintiffs is not within the constitutionally protected zone of privacy.

Laws which neither injure a "suspect class" nor impair a "fundamental interest" are evaluated under the general standard. Under this test, the law is valid so long as it rationally furthers a legitimate state interest. *San Antonio School District v. Rodriguez,* 411 U.S. 1, 16-17 (1973). The regulation and prevention of drug abuse through the Schedule II reporting requirements unquestionably furthers a legitimate state interest. *See* Argument I, *supra.*

However, assuming that the Schedule II filing requirements impinge on a person's fundamental right of privacy, such requirements are not unconstitutional where it can be shown that the state's interests are compelling and that its regulations operate within constitutionally permitted parameters.

A strict standard of judicial review is invoked only when a state law operates to the disadvantage of a "suspect class"[5] or when the state law impairs a "fundamental interest"; when such a law is challenged, it will be upheld if the state can show it is necessary to promote a compelling state interest. *San Antonio School District v. Rodriguez,* 411 U.S. 1, 16-17 (1973).

Where conflict arises between assertions of rights, there must be a balancing of the public interest and the individual right. In *California v. Byers* 402 U.S.

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[5]There are relatively few classifications which have been held to be suspect and among them are race, *McLaughlin v. Florida,* 379 U.S. 184 (1964); alienage, *Graham v. Richardson,* 403 U.S. 365 (1971); ancestry, *Oyama v. California,* 332 U.S. 633 (1947); and perhaps sex, *Reed v. Reed,* 404 U.S. 71 (1971).

424 (1971), a claim of self-incrimination was held insufficient to override the state's need for disclosures of names and addresses at the scene of car accidents. In *Breard v. Alexandria*, 341 U.S. 622 (1951), the constitutional protection of property rights yielded to a city's interest in protecting its citizens from annoyances. In *Prince v. Massachusetts*, 321 U.S. 158 (1943), the court upheld the state's right to prohibit distribution of literature by a minor against a claim of parental right and religious rights. Indeed, even freedom of speech is subject to reasonable regulation as to time, manner and place. By way of recent example, *Roe v. Wade, supra*, 410 U.S. at 155, 162-64, stated that there are circumstances under which abortions may be regulated. *See Roe v. Ingraham*, 480 F.2d 102, 108 (2d Cir. 1975); *Wolfe v. Schroering*, 388 F.Supp. 631, 639 (W.D. Ky. 1974).

Amicus respectfully submits that the challenged provisions achieve a proper balance of the plaintiffs' right of privacy with the government's interest in health regulation.[6]

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[6]*Amicus'* position finds support in the recent decision of *Association of American Physicians and Surgeons v. Mathews*, 395 F.Supp. 125 (N.D. Ill. E.D. 1975), affirmed, ... U.S. ...., 96 S.Ct. 388. In this case, plaintiffs brought an action to enjoin the Secretary of Health, Education and Welfare from implementing the professional standards review law and to have such law declared unconstitutional. After first holding that the statute does not bar a physician from practicing his profession but only provides standards for the dispensation of federal funds, the court held that these provisions do not infringe on the constitutionally protected right of privacy of plaintiffs.

Conclusion

For the foregoing reasons, *amicus curiae*, State of California, submits that the judgment of the district court should be reversed.

Respectfully submitted,

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1975

No. 75-839

ROBERT P. WHALEN, COMMISSIONER OF HEALTH OF THE STATE OF NEW YORK,
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v.

ROBERT ROE, *et al.*,
Appellees,

—and—

GEORGE PATIENT, *et al.*,
Intervenor-Appellees.

On Appeal from the United States District Court for the Southern District of New York

---

MOTION FOR LEAVE TO FILE BRIEF *AMICI CURIAE* AND BRIEF *AMICI CURIAE* FOR THE NATIONAL ASSOCIATION OF MENTAL HEALTH, THE AMERICAN PSYCHIATRIC ASSOCIATION, AND THE AMERICAN PSYCHOANALYTIC ASSOCIATION

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MOTION FOR LEAVE TO FILE BRIEF *AMICI CURIAE*

Counsel for the National Association for Mental Health, American Psychiatric Association, and the American Psychoanalytic Association, hereby respectfully move for leave to file the attached brief *amici curiae* in this case. The consent of the attorneys for the appellees has been obtained. The attorney for the appellants did not consent to the filing of this brief.

This case involves a constitutional challenge to a state statute which requires reporting and computerizing the names of all persons in the state legitimately using properly prescribed medication, the effect of which is to deter and inhibit persons from seeking needed medical and psychiatric services. The *amici* organizations, which are described more fully in the attached brief, represent more than a million medical practitioners and clients of mental health services who have an important interest in promoting the care and treatment of those in need of mental health assistance.

Effective provision of mental health services demands an atmosphere of trust and confidentiality in the psychotherapeutic relationship. This is important because inherent in effective psychotherapy is a frank discussion of the meaning of intimate and embarrassing acts, feelings, and fantasies which will not be revealed without assurances of confidentiality. Moreover, the mere disclosure that a person is engaged in psychotherapy, or is receiving medication from a psychiatrist, may result in social stigmatization, the loss of employment, and the disruption of personal lives. Their concern for confidentiality leads *amici* to conclude that unnecessary governmental record-keeping systems such as the one involved in the instant case will act as an improper deterrent to persons in need of mental health services. Accordingly, *amici* move this Court for leave to file the attached brief.

Respectfully submitted,

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BRIEF OF *AMICI CURIAE*

STATEMENT OF INTEREST OF *AMICI CURIAE*

The National Association for Mental Health (hereinafter NAMH) is a not-for-profit corporation founded in 1909 under the name of the National Committee for Mental Hygiene; it assumed its present name upon a merger with similar groups in 1950. NAMH is a volunteer organization the primary function of which is to promote citizen interest and activity on behalf of the

mentally ill and for the cause of mental health. The NAMH is comprised of 950 chapters throughout the nation and it has a total membership of approximately one million. The purposes of the Association are to improve attitudes toward mental illness and the mentally ill; to improve services for the mentally ill; and to work for the prevention of mental illness and to promote mental health.

The American Psychiatric Association, founded in 1844, is the oldest national medical society in the United States. Its 22,000 members comprise about 80 percent of all physicians who practice psychiatry and specialize in the treatment of emotional and psychological problems. It publishes the leading scientific journal in the field, *The American Journal of Psychiatry*, as well as the *Journal of Hospital and Community Psychiatry*, and a twice-monthly newspaper *Psychiatric News*. Recently, the Association has taken the lead in the formation of the new National Commission on Confidentiality of Health Records, Inc., and has created its own Task Force on Confidentiality as it Relates to Third Parties.

The American Psychoanalytic Association was founded in 1911. It is the largest national organization of medically trained psychoanalysts in the United States and is affiliated with the International Psychoanalytical Association. The Association has 2,270 members, and publishes a quarterly scientific journal, *The Journal of the American Psychoanalytic Association*. The purposes of the American Psychoanalytic Association include the study and advancement of psychoanalytic theory, the advocacy and maintenance of standards for the training and practice of psychoanalysts, and encouragement of research relevant to man's scientific knowledge and to human welfare. The Association has an "Ad Hoc Joint Committee on Confidentiality," and is, with the American Psychiatric Association, a participating and founding organization of the new National Commission on the Confidentiality of Health Records, Inc.

Collectively, the above organizations have a strong commitment to assuring citizen access to mental health services, and to assuring the consumers of such services that they can choose the treatment modality that will be most appropriate to their individual needs, free from unnecessary or overbroad governmental intrusions upon the necessary promise of confidentiality.

The instant case involves a state regulatory scheme, the effect of which has been to deter people from seeking medical services, including mental health services and demonstrates the negative impact and deterrent effects that the unnecessary collection, centralization, and computerization of medical information may have upon the voluntary clients of the mental health system. Amici seek to assist the Court in resolving the apparent conflict between the state's legitimate interest in regulating narcotics and the patients' legitimate need for privacy.

STATEMENT OF THE CASE

This class action brought on behalf of anonymous patients and their physicians successfully challenged the constitutionality of certain portions of the New York Controlled Substances Act. Specifically, those invalidated sections require physicians and pharmacists to report to the state the identities of all persons who are prescribed "Schedule II" medications by their physicians. N.Y. Pub. Health Law §§ 3331(6), 3332(2)(a), and 3333(4) (McKinney Supp., Jan. 1976).

"Schedule II" substances include a variety of drugs which are recognized as having legitimate medical uses. For example, "Ritalin" is used to treat hyperkinetic children or children with behavior problems; amphetamines are used to treat narcolepsy and epilepsy. Several of the drugs are frequently used in the practice of psychiatric medicine. Appendix, 148-49. The reporting pro-

visions require that every time Schedule II medication is prescribed, the prescription must be completed in triplicate on an approved state prescription form. A copy of the prescription, which includes the patient's name, must be sent to the New York State Department of Health, which retains it for five years. The pharmacy and the doctor are each required to keep one of the remaining copies for five years.

The copies of the prescriptions filed with the State Department of Health contain the name, age and address of the patient, information identifying the prescribing physician, the dispensing pharmacy, relevant dates, and the name of the drug dispensed and dosage levels. N.Y. Pub. Health Law § 3332.

Upon receipt of the copies of the prescriptions, the Department of Health has all the information coded and keypunched into discs and subsequently transferred to magnetic tapes for use by the computer. Appendix at 91-2. No special coding system is used to protect the names of prescription users, which are programmed directly onto the computer, together with the other information. Appendix at 92.

The computer produces various "printouts," including a printout of all patients who receive a prescription for Schedule II medication in excess of a 30-day supply. Appendix at 96-7. In addition, a printout of the medication history of any person in the computer is made available, upon request, to the Bureau of Narcotic Control. Appendix at 97. The computer printouts are not limited or regulated by the statute, regulations or policy directives of the State Department of Health. Nor are there limits to the uses to which the printouts may be put by the Department of Health. The computer does *not* contain the names of persons identified as "addicts" or "habitual users," N.Y. Pub. Health Law § 3331(1), as other pro-

visions of the Act are specifically applicable to such persons. Approximately 1.5 million prescriptions identifying their recipients are filed each year. Appendix at 92.

The patient-appellees objected to the filing and computerization of their names, claiming that the statute infringed their personal right to autonomously care for, and to seek effective treatment for, their health problems. The doctor-appellees claimed that the statutes interfered with and limited legitimate treatment choices for their patients. This unnecessary intrusion upon the patient-doctor relationship, it was contended, violated appellees' constitutional right to privacy.

After initially issuing a temporary order restraining the state's compliance with the statutes, the district court dismissed the complaint for want of a substantial federal question, *Roe v. Ingraham*, 357 F. Supp. 1217 (S.D.N.Y. 1973). The United States Court of Appeals for the Second Circuit, in an opinion by then Chief Judge Friendly, reversed this decision, 480 F.2d 102 (2d Cir. 1973), holding that "the individual's interest in keeping to himself the existence of his physical ailments and his doctor's prescriptions for them would lie rather close to the continuum [of constitutional privacy]," *id.* at 108. The Court of Appeals also found that plaintiffs-appellees were entitled to a continuation of the restraining order, and that a three-judge court should be convened to consider the constitutional claims.

A three-judge court was then convened. It dissolved the restraining order, denied cross-motions to dismiss, and required the Appellees to put on evidence in support of their claims, 364 F. Supp. 536 (S.D.N.Y. 1973). The parties thereupon entered into discovery, and produced a stipulation of facts, and agreements upon the issues to be tried, and the exhibits and witnesses to be used at such a trial.

Extensive expert and lay testimony and depositions by the Appellees established that, as a result of the filing and computerization of legitimate medicine users' names, patients' fears of improper disclosures deterred them from seeking necessary medical assistance, and encouraged them to discontinue proper use of scheduled medications. Appendix at 89-263. Testimony disclosed, for example, that parents had discontinued their children's use of Schedule II medication out of fear that they would be labeled addicts, Appendix at 123, 170-72. In at least one instance, the discontinuation of medication resulted in the hospitalization of a patient, Appendix at 141-43.

At the conclusion of the hearing, the three-judge court ruled for Appellees. The court acknowledged New York's legitimate interests in regulating addictive drugs, but concluded that the collection of patients' names contributed nothing toward the achievement of that purpose. It therefore held that "so much of the New York Health Law as requires reporting to state authorities in Albany the names and addresses of patients who receive Schedule II drugs as medication prescribed by duly licensed physicians is an unconstitutional interference with plaintiff's rights of privacy guaranteed under the Fourteenth Amendment." *Roe* v. *Ingraham*, 403 F. Supp. 931, 938 (S.D.N.Y. 1975).

The state's motion to this Court for a stay of the final order below was denied, —— U.S. ——, 96 S. Ct. 164 (1975). Probable jurisdiction was noted, —— U.S. ——, 96 S. Ct. 1100 (1976), and this appeal follows.

SUMMARY OF THE ARGUMENT

A narrow question is presented for review in this appeal—whether New York has made a sufficient showing to constitutionally justify its need for obtaining and computerizing the names of every person in the

state for whom certain medications with legitimate medical uses are prescribed. New York's authority to regulate narcotic substances is not at issue. Only the limited portion of the larger regulatory scheme that pertained to the collection of individuals' names was held to be unconstitutional by the court below. The propriety of that holding is the sole question before this Court.

The decision to seek appropriate health care for one's mind or body and to choose for one's self from among appropriate modes of available treatment is the kind of fundamental personal decision which is protected by the due process clause and by the personal right of privacy emanating from the Fourteenth Amendment. The process of entering into an "intimate personal relationship" with one's physician, and of relying on consultation with one's physician to make personal health care choices, is also a constitutionally protected aspect of privacy.

The court below took extensive evidence with regard to the effect of New York's requirement that the names of all patients using Schedule II drugs be filed and centrally computerized. It concluded that the challenged provisions seriously interfered with Appellees' constitutionally protected privacy by deterring and inhibiting them from voluntarily seeking needed medical assistance and by limiting the range of legitimate treatment modes available to them.

On their face the challenged requirements resemble other "neutral" record-keeping provisions, which do not interfere with personal privacy. However, the record in this case shows that the risk of disclosure of Appellees' names, coupled with the destructive social stigma that attaches to persons suffering from conditions for which Schedule II medications are prescribed, has de-

terred and limited Appellees' voluntary access to necessary and legitimate medical treatment.

In order to justify this interference with constitutionally protected privacy the Appellants must demonstrate that the challenged sections are necessary to accomplish a significant state purpose and are no more intrusive than necessary for the accomplishment of that purpose. While recognizing that the state had a significant interest in regulating Schedule II medications, the three-judge district court below found that "[h]aving the name of the person receiving the drug on the state form adds nothing" and that the challenged provisions had a "needlessly broad sweep." 403 F. Supp. at 937. It therefore held the challenged provisions violative of constitutional privacy. This decision is supported by the facts of record, is not clearly erroneous, and accordingly should be affirmed.

ARGUMENT

I. THE RIGHT TO SEEK APPROPRIATE CARE FOR ONE'S OWN BODY AND TO CHOOSE APPROPRIATE MODES OF TREATMENT BASED UPON CONSULTATION WITH ONE'S PHYSICIAN IS INCLUDED WITHIN A ZONE OF CONSTITUTIONALLY PROTECTED PRIVACY.

Appellees argue that the challenged provisions of Article 33 of the New York Public Health Law constitute a serious and unnecessary intrusion upon a zone of constitutionally protected privacy. At the outset this Court must decide whether the constitutional guarantee of personal privacy embraces the right to seek medical care and to choose appropriate modes of treatment for conditions such as hyperactivity, epilepsy, or depression. As the following analysis demonstrates, the privacy rights asserted by these Appellees are virtually identical to rights that this Court has already held to be constitutionally protected in its prior privacy decisions and should, therefore, be afforded similar protection.

One of the chief factors this Court has focused upon in prior decisions in which it has found a constitutionally protected right to privacy has been an individual's right to make decisions concerning important personal matters. *Griswold* v. *Connecticut*, 381 U.S. 479 (1965). In *Eisenstadt* v. *Baird*, 405 U.S. 438 (1972), this Court observed that:

> "If the right of privacy means anything, it is the *right* of the *individual*, married, or single, *to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person* as the decision whether to bear or beget a child." 405 U.S. at 453 (emphasis partly in original and partly added).

This Court's concern for autonomy in making health decisions is most clearly articulated in the "abortion" cases. In *Roe* v. *Wade*, 410 U.S. 113, 152 (1973), this Court held that a woman's right to terminate her pregnancy was a "fundamental" constitutional right subject to regulation only on the basis of a compelling state interest. *Doe* v. *Bolton*, 410 U.S. 179 (1973), recognized a pregnant woman's constitutional right to make the abortion decision on the basis of advice from her own physician without the approval of a hospital committee or the concurrence of other doctors.[1] As Justice Blackmun wrote for the majority in *Roe* v. *Wade*, *supra*:

> "[I]n a line of decisions . . . going back perhaps as far as *Union Pacific Co.* v. *Botsford*, 141 U.S. 250, 251 (1891), the Court has recognized that a right

[1] "The . . . *right* to receive medical care in accordance with [a] licensed physician's best judgment and the physician's right to administer it are substantially limited [by these requirements]," 410 U.S. at 197 (emphasis added).

> of personal privacy, or a guarantee of certain areas or zones of privacy, does exist under the Constitution. . . . These decisions make it clear that only personal rights that can be deemed 'fundamental' or 'implicit in the concept of liberty,' . . . are included in this guarantee of personal privacy. They also make it clear that the right has some extension to activities relating to marriage, . . . procreation, . . . contraception, . . . family relationships, . . . and child rearing and education, . . ." 410 U.S. at 152-53.

The Court went on to hold that the right of privacy was founded in the "Fourteenth Amendment's concept of personal liberty and restrictions upon state action" and was "broad enough to encompass a woman's decision whether or not to terminate her pregnancy." *Id.*

In *Planned Parenthood of Missouri* v. *Danforth*, —— U.S. ——, 44 U.S.L.W. 5197 (July 1, 1976), the Court voided statutory provisions that required wives to obtain spousal consent and minors to obtain parental consent prior to an abortion. The Court wrote that *Doe* and *Roe* "clearly establish that the State may not restrict the decision of the patient and her physician regarding abortions during the first stage of pregnancy," *id.* at 5201, and affirmed that the woman's autonomy in making the personal medical decision to have an abortion is sufficiently important to outweigh even the competing interests of a spouse or parent.

In finding that the right to privacy is broad enough to encompass abortion decisions, the Court stressed the adverse impact caused by denying a woman her ability to make this important personal decision. Among the "specific and direct" physical and psychological harms occasioned by the state's interference were the pressures of maternity and of child care, the emotional distress associated with an unwanted child, and the social stigma

of unwed motherhood. 410 U.S. at 153. Infringement upon one's ability to decide whether to seek or continue treatment with Schedule II medication can also result in "specific and direct" harms, as will be discussed in Section II, *infra*. And, like a woman's decision concerning the continuation of her pregnancy, an individual's decision concerning treatment for physical or emotional conditions is also an aspect of one's constitutionally protected "*freedom to care for* [*his or her*] *health and person.*" *Roe* v. *Wade*, *supra*, at 221 (Douglas, J. concurring) (emphasis in original).

A second factor present in decisions recognizing a constitutional right to privacy has been a "protected intimate relationship." *Paris Adult Theater I* v. *Slaton*, 413 U.S. 49, 66, n. 13. In *Griswold* v. *Connecticut*, *supra*, for example, the relationship between husband and wife was given constitutional protection because maintaining the privacy of this intimate personal relationship was central to the meaningful exercise of other constitutionally protected rights. While several of this Court's privacy decisions have concerned family relationships, they have strongly suggested a need to recognize that certain aspects of an individual's non-familial relationships, particularly those with his or her doctor, are also constitutionally protected, *see, e.g.*, *Eisenstadt* v. *Baird*, *supra*, at 453.

For example, in the "abortion" decisions the Court stressed the importance of allowing the woman opportunities to consult with her physician so that her right to make her decision could be meaningful and informed. In *Doe* v. *Bolton*, *supra*, this Court struck down a statute which required the woman's abortion decision to be approved by two physicians and a hospital abortion committee in addition to the recommendation of the pregnant woman's own consultant. The Court concluded that the woman's "right to receive medical care in accordance with her licensed physician's best judgment" was "sub-

stantially limited by that statutory provision," which was "unduly restrictive of the patient's rights." 410 U.S. at 197-98.[2] In his concurrence to *Roe* v. *Wade*, Justice Douglas placed special emphasis on the privacy of the relationship between patient and doctor:

> ". . . the right of privacy has no more conspicuous place than in the physician-patient relationship, unless it be in the priest-penitent relationship. . . . The right to seek advice on one's health and the right to place reliance on the physician of one's choice are basic to Fourteenth Amendment values." 410 U.S. at 219-20.

"Protected intimate relationships" were again emphasized in *Paris Adult Theater I* v. *Slaton*, *supra*, and *United States* v. *Twelve 200-Foot Reels of Super 8 MM Film*, 413 U.S. 123 (1973). In *Paris*, Chief Justice Burger, writing for the majority, noted that the privacy right recognized by earlier Court decisions "encompasses and protects the personal intimacies of the home, the family, marriage, motherhood, procreation and child rearing." 413 U.S. at 65. In upholding a Georgia regulation of allegedly obscene materials exhibited at an "adult theater," Chief Justice Burger distinguished *Stanley* v. *Georgia*, 394 U.S. 557 (1969), which had recognized a limited right of privacy to possess obscene materials in the home, from other cases recognizing broader privacy rights "arising from a special relationship." 413 U.S. at 66-7. As the Court held in *Paris*,

> "The protection afforded by *Stanley* v. *Georgia* is restricted to a place, the home. In contrast, the constitutionally protected privacy of family, marriage, motherhood, procreation and child-rearing is not

[2] "Indeed," wrote then Chief Judge Friendly in a prior decision in this case, "there is language in *Doe* v. *Bolton* from which it could be argued that the Court has already taken the step of extending constitutional protection to the privacy of the doctor-patient relationship." 480 F.2d 102, 108, n. 8.

> just concerned with a particular place, but with a *protected intimate relationship.* Such protected privacy extends to *the doctor's office*, a hospital, the hotel room, or as otherwise required to safeguard the right to intimacy involved." 413 U.S. at 66, n. 13 (citations omitted and emphasis added).

In *United States* v. *Twelve 200-Foot Reels of Super 8 MM Film*, *supra*, Chief Justice Burger reanalyzed the list of protected intimacies as "a *sphere* of constitutionally protected privacy, such as that which encompasses the *intimate medical problems* of family, marriage and motherhood." 413 U.S. 126, n. 4 (emphasis added).

Significantly, the medication decisions which plaintiffs seek to have constitutionally protected in this case also fall within other zones of activity where this Court has specifically recognized constitutional limitations upon the state's power to substantively regulate conduct. As noted in *Paul* v. *Davis*, —— U.S. ——, 96 S. Ct. 1155, 1166 (1976), "the activities detailed as being within [constitutionally protected privacy are] . . . matters relating to . . . family relationships, and child rearing and education." In this case, the record below establishes that parents of a four-year-old hyperkinetic child receiving Ritalin were forced to consider taking him off the medication, even though their physician believed it to be in the child's best interest. Appendix at 115-18. A medical decision to give an amphetamine to a hyperactive child falls squarely within the zone of constitutional privacy relating to family relationships, child rearing, and education.[3]

[3] An additional aspect of privacy—one's right to selectively disclose personal information without undue governmental interference—is also raised by the facts of this case. Both the three-judge district court and the Second Circuit, in different stages of the proceedings below, focused upon this "disclosure" aspect of privacy. As the district court noted, "an individual's physical ills and disabilities, the medication he takes, the frequency of his medical

Each of the basic factors outlined by this Court in earlier cases defining constitutionally protected privacy —a fundamental personal decision, an intimate relationship, family and child-rearing matters—are present in this case. Accordingly, this Court should hold that an individual's right to seek and continue appropriate medical treatment based upon consultation with one's physician is constitutionally protected.

II. NEW YORK'S REQUIREMENT THAT CERTAIN PRESCRIPTIONS BE REPORTED AND COMPUTERIZED SERIOUSLY INTERFERES WITH APPELLEES' CONSTITUTIONAL RIGHT TO PRIVACY IN SEEKING APPROPRIATE CARE FOR THEIR OWN MINDS AND BODIES AND IN CHOOSING TREATMENT AFTER CONSULTATION WITH THEIR PHYSICIANS.

Appellants contend that the challenged statutory requirement is simply a record-keeping procedure which does not directly prohibit or limit any activity by Appellees. On this basis, Appellants would distinguish the instant case from the "abortion" decisions and other cases in which this Court has voided statutes that directly infringed constitutionally protected privacy. Upon inspection, however, this "distinction" fails because the challenged New York provisions result in the same kind of deterrence and interference with protected privacy (although here in the context of medication decisions)

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consultation are among the most sensitive of personal and psychological sensibilities. One does not normally expect to be required to have to reveal to a government source, at least in our society, these facets of one's life. Indeed, generally one is wont to feel that this is nobody's business but his doctor's and his pharmacist's." 403 F. Supp. at 937. Chief Judge Friendly, writing for a unanimous Second Circuit panel, stressed "the individual's interest in keeping to himself the existence of his physical ailments and his doctor's prescriptions for them." 480 F.2d at 108.

that was presented by direct statutory prohibitions in the abortion cases.[4]

Obviously, the Appellants did not intend to collect this information for the express purpose of deterring its citizens from seeking medical advice. But the Constitution provides protection "even if any deterrent effect on the exercise of [constitutional rights] arises, not through direct government action, but indirectly as an unintended but inevitable result of the government's conduct . . ." *Buckley* v. *Valeo*, —— U.S. ——, 96 S. Ct. 612, 656 (1976).

The New York statute is strikingly similar to the Missouri statute preventing the use of Medicaid funds for abortions not medically required that was challenged in *Singleton* v. *Wulff*, —— U.S. ——, 44 U.S.L.W. 5213 (July 1, 1976). Missouri did not directly prohibit abortions; it permitted the operation but refused to spend public funds to pay for a needy woman's abortion. In holding that physicians had standing to challenge the statute, a plurality of the Court, looking to the *consequences* of that regulation, noted that "an impecunious woman cannot easily secure abortion," and therefore the "woman's exercise of her right . . . is . . . necessarily at stake here." 44 U.S.L.W. at 5216.

As will be demonstrated below, it is the stigmatizing consequences of disclosure of the use of certain Schedule

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[4] Appellants effort to characterize this as a "narcotics control case" is likewise without merit. Schedule II includes many substances which are recognized as having legitimate medical uses, and the patients herein are all persons for whom these medications have properly been prescribed. The medications are frequently used by physicians and psychiatrists to ameliorate the chronic pain and disabling effects of schizo-affective disorders, epilepsy, narcolepsy, and childhood hyperkinesia, among other problems. Appendix at 148-49, 204-05. Moreover, "addicts" and "habitual users" are specifically *not* included in these recordkeeping provisions. N.Y. Pub. Health Law § 3331(1).

II drugs that distinguishes the regulations under attack from truly neutral regulations such as those governing the filing of birth and death certificates or registration with the Social Security Administration. *Cf.* Brief of Appellants at 18. The record below establishes that some patients were deterred from seeking medical advice, and that others discontinued treatment or selected less useful treatment alternatives rather than continue to use Schedule II medications which would require reports to the State Department of Health.[5] They realistically feared that reporting and computerizing the names of legitimate Schedule II medication users might result in the disclosure of this private information, and therefore subject them to being improperly and unfairly stigmatized as criminals, drug addicts, narcotics abusers, and/or persons with embarrassing medical or psychological problems. The three-judge court properly concluded that "[t]here is no question but that the statutory requirement challenged here intrudes upon and interferes with the doctor-patient relationship," 403 F. Supp. at 937.

Damaging stigma may attach both to users of some of the Schedule II drugs themselves, and to persons having the underlying physical and psychological conditions for which some of these drugs are prescribed. Persons labeled "mentally ill" often face social stigma equivalent

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[5] The operation of the challenged New York provisions is described fully in the Statement of the Case, pages 5 to 7, *supra*. In brief, whenever a Schedule II medication is prescribed, the physician must complete a triplicate prescription form. This form contains the name, age, and address of the patient, the name and amount of the medication dispensed and the level of dosage. One of these forms is forwarded to the State Department of Health, which retains it for five years. The information on the form is coded and transferred to magnetic tapes for use by a computer. The computer produces monthly "printouts," including one that lists by name all patients who have received a prescription for a Schedule II medication in excess of a 30-day supply.

to, or greater than, that recognized by this Court as affecting unwed mothers in *Roe* and *Doe*, *supra*, 410 U.S. at 153. "Some diagnostic terms have discriminatory social connotations and cause injury . . . if made known to others." American Psychiatric Association, *Confidentiality and Third Parties* iv (Task Force Report No. 9, 1975). As a recent Harvard Law Review Developments Note explains:

> ". . . a former mental patient may suffer from the social opprobrium which attaches to treatment for mental illness and which may have more severe consequences than do the formally imposed disabilities. Many people have an 'irrational fear of the mentally ill.' The former mental patient is likely to be treated with distrust and even loathing; he may be socially ostracised and victimized by employment and educational discrimination. Finally, the individual's hospitalization and post-hospitalization experience may cause him to lose self-confidence and self-esteem." Note, "Developments in the Law, Civil Commitment of the Mentally Ill," 87 *Harv. L. Rev.* 1190, 1200 (1974) (footnotes omitted).

The APA Task Force Report, *supra*, catalogues reports from psychiatrists of injuries caused their clients by the stigmatizing disclosure of psychiatric treatment. These incidents include, *inter alia*, the loss of employment, divorces, loss of insurance coverage and benefits, and the avoidance of necessary treatment out of fear of disclosure. Task Force Report, *supra*, at 53-59.

Revelation of the names of medicine users and centralization of data in a computer enhances the risks that information will be improperly circulated and used out of context. As the record in this case shows, if centralized reporting increases the risk of disclosure with consequent stigma, the risk that persons needing psychotherapeutic treatment will be deterred from seeking that treatment correspondingly increases.

James Moe testified that he had taken his child off of a Schedule II medication because he feared that the state would develop a "long file in a narcotics and dangerous drug context," Appendix at 123. Martha Patient testified that, out of fear of the computer, she discontinued use of her properly prescribed medication for migraine headaches until severe pain forced her to renew her prescription. Appendix at 141-43. Jane Poe believed she would be labeled a "dope addict." Appendix at 138-39. George Patient, suffering from cancer, tried to substitute medication not on Schedule II, and finally resorted to the subterfuge of purchasing the Schedule II medication in a neighboring state that did not require central registration. Appendix at 87-88. Mary Doe, the mother of a nine-year-old hyperkinetic child, testified that she had taken her [illegible] off of his prescribed Schedule II medication because she feared he would be "branded for life" as a drug abuser. Appendix at 170-72.

The questionable security of New York's computer system heightens the potential for the improper use or disclosure of the computerized information. No special coding system is used to protect patients' names. A printout of the entire medication history of any name in the computer is routinely made available, upon request, to the Bureau of Narcotic Control. There is no statutory regulation of the use of the information, nor has the Department of Health promulgated policies regarding the storage, use, or dissemination of this information. Unrebutted evidence of record established that there was a substantial risk of improper disclosures of the prescription data gathered by New York State because (1) *physical* security, *i.e.*, guards, locks, alarms, was inadequate; (2) *procedural* security, *i.e.*, employee clearance regulations, in-service training, was inadequate; and (3) *data* security,

i.e., protection, presentation, and duplication of magnetic and printed information, was deficient. Appendix at 302-35.[6]

Given the serious stigma associated with disclosures of the use of certain Schedule II medications, and the questionable computer security system, it is not unreasonable for Appellees to be deterred from seeking medical care, even where it would be otherwise indicated. Several doctors testified that patients, when advised of the centralized reporting requirements, expressed "shock, fear, and concern," 403 F. Supp. at 935. They testified further that as a result of the reporting requirements, their professional relationships with these patients had been adversely affected, and that individuals who might need medication would be "dissuaded" from "undergoing treatment." *Id.* at 934.

The quality of the psychotherapeutic relationship is substantially undermined when the patient learns of the existing potential for governmental intrusion. "[S]ecurity from abuse of privacy forms a condition without which it would be difficult to practice psychiatry and psychotherapy at all." American Psychiatric Association, *Confidentiality and Third Parties, supra,* at iv.[7] The "very essence" of psychotherapy "is confidential personal reve-

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[6] Because the court below found the state's "need" to collect the names of prescription users in order to accomplish its legitimate drug regulation functions to be minimal (*see,* discussion at Section III, *infra*), it found it unnecessary to rule upon the adequacy of the operative state procedures to insure confidentiality, 403 F. Supp. at 938.

[7] ". . . there is wide agreement that confidentiality is a *sine qua non* for successful psychiatric treatment," Group for the Advancement of Psychiatry, *Confidentiality and Privileged Communications in the Practice of Psychiatry* 82 (Report No. 45, 1960); ". . . the psychiatrist must instill complete confidence . . . that he will not reveal such secrets to others," N. Spingarn, *Confidentiality: A Report of the 1974 Conference on Confidentialty of Health Records* 2 (1975).

lations about matters which the patient is (and should be) normally relutcant to reveal or discuss." R. Slovenko, *Psychotherapy, Confidentiality and Privileged Communication* 40 (1966). For these reasons, "[t]he threat to confidentiality is of even greater concern to psychiatry than to the rest of medicine." N. Spingarn, *Confidentiality: A Report of the 1974 Conference on Confidentiality of Health Records, supra,* at 2.

Not only do the challenged provisions deter persons from seeking out or continuing necessary psychotherapeutic treatment, but they also severely limit available treatment options. Depending upon a person's needs and condition, and the practitioner's skills and training, a person and his or her psychiatrist may choose to undergo some form of psychotherapy, a "somatic" therapy, or to be voluntarily hospitalized. Perhaps the most common option, however, and one often used in conjunction with another treatment modality, is the prescription of a psychotherapeutic medication, "a major weapon in the armamentarium of the physician." Parry, Balter, Mellinger, Cisin, Manheimer, "National Patterns of Psychotherapeutic Drug Use," 28 *Arch. of Gen. Psychiatry* 769 (1970). *See also* 1 L. Wolberg, *The Technique of Psychotherapy* 91 (2d ed. 1967). A practitioner knowing that he or she must report every patient's name to a central computer bank may be hesitant to suggest the use of the scheduled medication. A patient advised of the reporting requirement may likewise be inhibited from using such medications, regardless of the clinical indications favoring its use. The result is the harmful reduction of the patient's legitimate treatment options. Indeed, the record in this case shows that Mary Doe took her nine-year-old son off of prescribed medication despite her physician's advice, Appendix at 171. Martha Patient's discontinuation of her Schedule II medication resulted in her hospitalization. Appendix at 142.

In sum, there can be no doubt that the challenged New York record-keeping system has interfered with Appellees' legitimate exercise of protected constitutional rights.

III. NEW YORK HAS FAILED TO MEET THE CONSTITUTIONAL STANDARD FOR JUSTIFYING ITS INFRINGEMENT UPON APPELLEES' CONSTITUTIONAL RIGHT TO PRIVACY.

A conclusion that a state regulation may be infringing upon constitutional rights does not, of course, end a court's inquiry into the permissibility of that infringement. The right to privacy, like other constitutional guarantees, "is not unqualified and must be considered against important state interests in regulation." *Roe* v. *Wade, supra,* 410 U.S. at 154. When these interests "become sufficiently compelling," *id.*, limited governmental incursions upon the right may be justified.[8]

Without question, the regulation of medication is a proper and legitimate governmental activity. It is not enough, however, that a state have some legitimate *general* purpose:

> "In pursuing that important interest, the State cannot choose means that unnecessarily burden or restrict constitutionally protected activity. Statutes affecting constitutional rights must be drawn with precision." *Dunn* v. *Blumstein,* 405 U.S. 330, 343 (1972).

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[8] This principle is reflected in the limitations upon a person's expectation of privacy in his or her confidential relations with a physician. Physicians and psychotherapists have a duty to report epidemics, communicable diseases, and other conditions where they believe a substantial risk of imminent physical injury to the patient or to others exists. *See, e.g.,* Allen, Ferster, and Rubin, *Readings in Law and Psychiatry* 239-250 (1975). These exceptions to the rule of confidentiality are justified either by the lack of privacy expectation in the communication, as when it relates to criminal activity, or by the existence of exigent circumstances that pose an imminent danger to the community.

See also, Shapiro v. *Thompson*, 394 U.S. 618 (1968); *Sherbert* v. *Verner*, 374 U.S. 398 (1963); *Shelton* v. *Tucker*, 364 U.S. 497 (1960). Thus, as District Judge Carter noted at an earlier stage of these proceedings:

> "The critical question is whether the objective which the regulation seeks to accomplish is necessitated by a subordinating state interest jusifying the *degree* and *consequences* of the result in personal intrusion." 364 F. Supp. 536, 546 (emphasis added).

In *Doe* v. *Bolton*, *supra*, the state conditioned its sanctioning of a woman's decision to abort her fetus on the prior approval of two physicians, as well as a hospital committee, and limited the place in which the operation could be performed to certain licensed hospitals, 410 U.S. at 184. This Court struck down those statutory conditions because there is "no constitutionally justifiable pertinence" in conditions which unduly limit "a woman's right to receive medical care in accordance with her licensed physician's best judgment." 410 U.S. at 197.[9] A review of this record shows a similar lack of "constitutionally justifiable pertinence" in the challenged requirements in the instant case.

Prior to its final decision the three judge district court declined to issue preliminary relief because the evidence produced at that time was insufficient to establish that "the consequences of the resulting intrusions are not justified when considered against the state's interest." 364 F. Supp. at 546. Instead, the court called for an evidentiary hearing on the merits to offer plaintiffs the opportunity to demonstrate "that the computerization of names

[9] Specifically, the Court found that the licensure requirements did "not relate to particular medical problems and dangers of the abortion operation," 410 U.S. at 194; that the approval "by a committee once removed from diagnosis is basically redundant," *id.* at 197; and that the two-doctor certification for abortions was the only instance of the legislature requiring "confirmation by two other physicians" for voluntary medical treatment, *id.* at 199.

is not necessary for the accomplishment of the state's goals, that the controls developed by the state are inadequate to protect against unauthorized disclosure of the computerized information and that the injury to the plaintiffs resulting from the implementation of this system as centralized filing is sufficiently serious to overcome any competing state interest." *Id.* at 546-47.

Only after Appellees had the opportunity to present evidence on these issues was the three-judge district court finally persuaded that the state regulatory scheme —although it did foster a legitimate state purpose—had a "needlessly broad sweep." 403 F. Supp. at 937.

The purpose of New York's enforcement scheme is to regulate the physician and the pharmacist who store, control, and dispense Schedule II medication. The evils the statute aims to curb are (a) professional abuses, such as overprescription and overdispensing of drugs, and (b) illegal diversion of drugs, such as thefts from pharmacies, stolen prescription blanks, or forged signatures. Appendix at 94. It certainly is proper, therefore, for the state to require physicians and pharmacists to keep records and to file reports. But when, as here, the state also demands that the name, age, address, type, and amount of drug prescribed for every medication user be automatically filed in a state-wide computer, it has gone far beyond its legitimate need to prevent professional abuse and illegal diversion.

The state *stipulated* in the district court that the only reason it required the names of patients was to identify persons who, using the same name, went from doctor to doctor to obtain an illegal cache of medication. Appendix at 95. The court below found that the sole purpose for collecting the names of patients was "to identify individual patients who without using an alias went from doctor to doctor to secure Schedule II drugs and those individuals who secure more than a 30-day supply in any

single month." 403 F. Supp. at 937. Appellants have not provided this Court with any additional reasons justifying the collection of every patient's name (Brief for Appellants at 26-30) and indeed no other reason exists. The court below found as a matter of fact that the state's "need" for the names was illusory, evidenced by the fact that only one person suspected to have secured multiple prescriptions in a particular month had been discovered during the program's four-year existence, 403 F. Supp. at 934.[10] As a matter of common sense, it is unlikely that a person seeking to hoard drugs for personal consumption or sale would use his or her real name and address, or use the same name each time he or she visited a different doctor. As the three-judge district court held, the speculative returns of the challenged statutes were "too great a price to pay for such a small yield." *Id.*

Significantly, most regulatory schemes in other jurisdictions do not require the filing of patient names on prescriptions. The Uniform Controlled Substance Act (1970), which is similar to the narcotic control statutes in forty states, specifically provides that a medical practitioner or researcher "is not required or compelled to furnish the name or identity of a patient or research subject. . . ." Section 504(c). Although the act requires that prescription records be kept, they are to be maintained by individual practitioners, and can be obtained by the state only through a warrant, unless there is consent, or an emergency, § 502(b)(4). Thirty-six of the forty states that have modeled their statutes on the Uniform Act do not require the reporting of patients'

[10] Appellants have now made vague references to an additional 45 "referrals" uncovered in September 1975, Brief of Appellants at 27, note * * *. Since these unverified figures are not part of the record, they should not be considered by this Court. At the very most, any consideration of this alleged new information would justify a remand to the district court, and not a reversal of its decision.

names to a centralized data bank.[11] Nor does the Federal Drug Abuse Act, 21 U.S.C. § 801, *et seq.* (1972), require the centralized filing of prescriptions or the revelation of patients' names.

The Appellants argued below that computerizing records with patient names was really no different from the prior regulatory requirement that prescriptions with patient names had to be kept by pharmacists and made available for state inspection. The three-judge district court rejected this argument, observing that "the intrusion here is not only more immediate, its impact is greater." 403 F. Supp. at 938. As that court aptly noted, "a name on a prescription in the files of one of many thousand pharmacists in the state of New York is entirely different from one's name on a form in Albany which is transferred to computerized records and stored for instant retrieval." *Id.* The potential for inappropriate disclosure or actual misuse that exists whenever information is gathered is greatly magnified by the creation of a central depository of medical information. A central data bank poses substantial risks of human error, mechanical malfunction, or corruption. As the 1974 Conference on Confidentiality of Health Records concluded, "the administrative conveniences provided by the high degree of computerized information centralization gives those who control the recording and preservation of personal data an unprecedented power over us, and are subject to abuse." Spingarn, *Confidentiality: A Report of the 1974 Conference on Confiedentiality of Health Records, supra,* at 4.

The challenged New York provisions differ markedly from other record-keeping and reporting requirements recently approved by this Court. In *Planned Parenthood*

[11] The statutes are set forth in Appendix A to the Memorandum of Appellees Roe, *et al,* in Opposition to the Motion for a Stay and need not be repeated here.

of Missouri v. *Danforth*, *supra*, the state required health facilities and doctors to keep certain records relating to abortions. Significantly, these records were retained by the facility or physician; they were *not* centrally filed and computerized; and the statute did *not* require that each patient be identified by name. Because these records were used solely for statistical purposes to develop health care information, they had "no legally significant impact or consequence . . . on the physician-patient relationship." 44 U.S.L.W. at 5205. The Court noted, however, that even this system "perhaps approach[ed] permissible limits," *id.*

New York's law is by no means so narrow and limited. By contrast with the record-keeping system in *Planned Parenthood*, *supra*, New York's provisions require the central computerization of all records, require that every patient be identified by name, and thus do have a "legally significant impact . . . on the physician-patient relationship." Moreover, it would be improper for the Court to "assume" here, as it did in *Planned Parenthood*, that "the records will not be utilized in such a way as to accomplish . . . unconstitutional restriction[s]," *id.*, because there is overwhelming evidence to the contrary in this record.

Buckley v. *Valeo*, *supra*, involved a challenge to various provisions of a campaign financing law that, *inter alia*, required public disclosure of all individual contributions to presidential candidates. The Court noted that although such disclosures clearly "burdened" or "deterred" the exercise of constitutional rights, 96 S. Ct. at 658, the challenged provision was justified by compelling interests of the highest order—the prevention of election corruption and the opening of the election process to public view. In upholding the disclosure provision, the Court specifically found (indeed, it had been conceded) that disclosure requirements "appear to be the *least restrictive* means of curbing the evils . . ." *id.* (emphasis added).

By contrast, New York has hardly selected the "least drastic means" available for controlling drugs by requiring the massive disclosure and computerization of the name of every legitimate user of certain medications. In fact, the "need" for the collection and retention of the name of every prescription user in the state is illusory. According to the district court, "[h]aving the name of the person receiving the drugs on the State's form adds nothing." 403 F. Supp. at 937. Thus, the New York law is fraught with all the dangers of the federal campaign law, but is saved by none of that law's redeeming justifications.[12]

In sum, although New York has a legitimate state interest in regulating the distribution of Schedule II medication, the provisions challenged herein intrude upon, burden, and deter the exercise of its citizens' constitutionally protected privacy rights. Appellants must bear the heavy burden of demonstrating that its actions are the least intrusive means consistent with achieving its legitimate regulatory purpose. After extensive discovery and briefing, and based on a substantial record, the three-judge court found the challenged provisions to have a "needlessly broad sweep." 403 F. Supp. at 937. This conclusion is consistent with this Court's previous decisions, it is supported by the evidence adduced below, and it should be affirmed.

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[12] Similarly, in United States v. Miller, —— U.S. ——, 96 S. Ct. 1619 (1976), the Court upheld the record-keeping requirements of the Bank Secrecy Act. But those records are not centrally compiled. There is no automatic blanket filing requirement; when information is desired it is obtained pursuant to a subpoena seeking limited, or reasonably particularized, information. 96 S. Ct. at 1624. No such efforts to accommodate privacy rights appear in the instant statutory scheme.

CONCLUSION

For the foregoing reasons, *amici* respectfully urge this Court to AFFIRM the decision of the court below.

Respectfully submitted,

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